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**“Enjoy your baby” Internet-based CBT for mothers
with babies: a feasibility randomised control trial**

And Clinical Research Portfolio

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Submitted in partial fulfilment of the requirements for the degree
of Doctorate in Clinical Psychology (DClinPsy)

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In loving memory of my dad.

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Chapter 1- Internet CBT based self-help to assist mothers to manage their mood in the perinatal period: A systematic review and meta-analysis.

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ABSTRACT

Background: Research suggests 19.2% of mothers experience depression during the perinatal period, representing a global public health problem. CBT is recommended for postnatal depression; however barriers can prevent access to mental health services. CBT-based internet self-help could potentially remove some of these.

Objective: Identify, evaluate and synthesise existing literature on internet CBT based self-help interventions for mothers' mood in the perinatal period.

Method: 9 referencing databases (EMBASE, Medline, CINAHL, PsychINFO, MIDIRS, Cochrane, TRIP, Web of Science and EThOS) were searched on the 12th and 13th of May 2016 and studies identified that included an internet-based self-help intervention helping mothers manage their mood in the perinatal period. Studies were excluded if they did not focus on mood, were not internet-based, or included mothers of children over 1 year old. The Cochrane Risk of Bias tool was used to assess bias in relation to the true intervention effect in the studies. Data were synthesised and a meta-analysis conducted.

Results: 4 RCTs met inclusion criteria. They offered a treatment in the postnatal period, for postnatal depression and had a low risk of bias. Effect sizes show moderate and high effects in favour of the treatment groups.

Limitations: This review highlights the paucity of data in this area and the small number of studies available for inclusion. Included studies were limited to English language only and follow-up data rather than the mean and standard deviation of change was used in the meta-analysis.

Conclusions: Outcomes from postnatal studies of internet interventions are wholly positive and suggest further confirmatory research be completed to contribute to the evidence base for use in everyday services. A larger well-designed pragmatic trial that can assess delivery robustly is recommended. Additional research is also required to establish effects of interventions in the antenatal period to identify whether postnatal depression can be avoided or ameliorated.

Key words: Internet, self-help, postnatal depression, perinatal depression, CBT, low intensity, computerised CBT, cCBT.

INTRODUCTION

A systematic review of the prevalence of perinatal depression reported that in the period during pregnancy and the first three months postpartum 19.2% of women have a depressive episode, including 7.1% experiencing a major depressive episode [1]. A meta-analysis [2] reported a 13% prevalence rate of postnatal depression (PND) with increased prevalence (27%) in minority ethnic women [3]. Almond [4] described PND as a global public health problem, adding that the effects can extend to the child and the mother's partner. Untreated PND can have a negative effect on the development of the relationship between a baby and their mother [5, 6]. This can have a long term negative impact on children, for example children who have anxious or depressed mothers are at greater risk of emotional and behavioural difficulties [6] and perinatal distress can have adverse effects on a child's cognitive development [7].

A Cochrane meta-analysis showed Cognitive Behavioural Therapy (CBT) can have helpful outcomes for mothers experiencing PND [8] and this is recommended in both SIGN and NICE guidelines [5, 9]. There is no evidence cited to date, in national guidelines, that supports the use of computerised interventions for this group [5]. However, Computerised Cognitive Behavioural Therapy (CCBT) is recommended in NICE [10] and SIGN [11] guidelines for mild to moderate depression. Its effectiveness has also been shown in areas such as insomnia [12] and anxiety and depression in youths [13].

Standardised depression packages in adult mental health services do not take into account the specific challenges faced by new mothers. For example, a new mother has little control over her sleep; this has been a criticism of many internet-based packages offering approaches for adults with depression in general rather than taking into account the challenges of having a young child [14]. Delivery of these interventions in a guided self-help way can increase use of online resources by individuals [15]. However, access remains a key issue. Kohn and colleagues [16] describe a difference in the rates of depression and anxiety, and presentation at mental health services: 53.6% of people with symptoms of depression and 57.5% of those with symptoms of generalized anxiety disorder do not present to services. Community surveys confirm that members of the

public give higher endorsements to self-help, voluntary sector and local support networks than more formal NHS resources [17]. McQuaid and Homewood [18] report they faced challenges obtaining referrals from GP's and Health Visitors (HV) when trying to establish a group psychological intervention for mothers. Research [19] identifies a number of factors which contribute to mothers' reluctance to disclose difficulties with low mood to their GP or HV, including concerns they would be perceived negatively, fear of having their baby removed, and difficulty getting appointments with their GP. In addition, Dennis and Chung-Lee [20] found mothers often choose not to take anti-depressant medication for fear of transmission via breast milk or side effects. It is hoped internet interventions that can be freely accessed will allow mothers to "self-refer", therefore reaching mothers who have not presented, or taken up such help via a health service setting.

Two recently published systematic reviews [21, 22] have synthesised information on web-based interventions for mothers in the perinatal period. These reviews have included studies which focussed on depression, anxiety, grief, stress and posttraumatic stress disorder. It could be argued that PND is distinct and should not be combined with data from studies such as these, for example, where mothers have lost their baby and are perhaps experiencing a bereavement rather than PND. Furthermore these reviews did not focus specifically on CBT and included a number of other interventions such as stress management. Additionally, data from randomized controlled trials (RCTs) have been combined with data from weaker study designs; standards recommend this should be avoided.

A more thorough and focused search to identify the evidence base for internet delivered CBT for mothers in the perinatal period was indicated. Given recent developments in this area, it has been possible to include additional, more robust studies in the current review. In contrast to previous reviews and in order to adhere to standards of best practice, this review has included RCTs only and has used the Cochrane Risk of Bias tool [23] as opposed to a quality checklist or rating scale. Assessing for risk of bias is purported to be a more transparent way of assessing risk and avoids the pitfall of having to assign weights as is required in scales. It can be difficult to justify assigned weights and the Cochrane Collaboration [23] discourage use of these on the basis that scales are not

evidence based. Additionally Cochrane [23] report that checklists can often cover not only risk of bias in design but also in the reporting of the results which has no bearing on the internal validity of the study.

Aim: To evaluate evidence for the effectiveness of internet self-help interventions to help mothers in the perinatal period manage their mood.

METHODS

Search strategy

The reporting of this review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [24]. The PICOS method was used to identify the parameters to define the search:

- Population- mothers or pregnant women in the perinatal period.
- Intervention- internet CBT based self-help.
- Condition- depression.
- Outcome- effect of intervention on mood.
- Study design- RCT.

In accordance with recent literature the perinatal period is defined here as pregnancy to 1 year postpartum.

The databases searched and search terms were identified following a review of recent systematic reviews, and discussions with supervisors and a librarian. EMBASE, Medline, CINAHL, PsychINFO, MIDIRS, Cochrane, TRIP, Web of Science and EThOS databases were searched on the 12th-13th of May 2016. No limits were placed on dates. The reference lists of included articles were reviewed, as were two key journals in this area- Internet Interventions and the Journal of Medical Internet Research (JMIR). The publication history of two key authors in this area were also reviewed; Cindy Lee Dennis and Jane Morrell. Both published and grey literature were searched to maximise results and to try to account for publication bias such as the file drawer effect; the suggestion that studies which are not statistically significant are less likely to be published. A number of research protocols were also identified during searches and authors were emailed to

enquire about future publications. Responses were received from the majority of authors, none of whom reported their results would be published within a time frame suitable for this review. Although conference proceedings, published abstracts and commentaries were screened, only peer reviewed published articles that met criteria were included in the final review.

Key word searches (shown below) were linked using the Boolean operators “AND” and “OR”. Truncation, indicated by the asterisk, was used to ensure any word endings following the truncation would be identified.

Mother OR mum OR mom OR pregnan* OR wom?n OR maternal

AND

Self-help OR self-care OR bibliotherapy OR psychoeducation OR cognitive behavi* therapy OR CBT

AND

Online OR electronic OR telemedicine OR telecare OR telehealth OR teleconsultation OR tele-rehabilitation OR computer OR internet OR web OR virtual OR ccbt OR iCBT OR ehealth OR telepsychology

AND

Postpartum depress* OR postnatal depress* OR puerper* OR prenatal OR perinatal OR antenatal OR postnatal OR postpartum OR neonatal

AND

RCT OR randomi* control* trial

Inclusion/exclusion criteria

Titles of papers were screened initially, followed by reading abstracts and if required, full papers in order to determine eligibility. Included studies were restricted to RCTs as this method is agreed to be the gold standard of clinical research.

Studies were included if:

- They were RCTs, or a pilot or feasibility RCT.
- They evaluated the effectiveness of an internet or electronic intervention to help mothers manage their mood in the perinatal period.

Studies were excluded if:

- They were not written in English.
- They did not focus on depression or include a mood measure.
- They included mothers who did not have a child under 1 year old (e.g. mothers with children over 1 year old, or mothers who miscarried or had still births).

Quality appraisal

In accordance with best practice guidelines [23, 24] the Cochrane Risk of Bias tool [23] was used to determine the credence that should be given to the reported results in the studies included in this review. This tool focuses on 6 areas:

1. Random sequence generation.
2. Allocation concealment.
3. Blinding of participants and personnel.
4. Blinding of outcome assessment.
5. Incomplete outcome data.
6. Selective reporting.

All included studies were reviewed by the author and a colleague, disagreements were resolved through discussion until 100% agreement was reached. A third opinion was not required.

Synthesis

Data extraction was completed and information summarised into a narrative. A meta-analysis has been completed using RevMan 5.3 software [25]. Due to the data available, this was completed using follow-up data rather than the mean and standard deviation of change which would have been more statistically robust.

Calculation for Cohen's *d* effect size:

$$d = \frac{M_{group1} - M_{group2}}{SD_{Pooled}}$$

Where:

$$SD_{Pooled} = \sqrt{(SD^2_{group1} + SD^2_{group2})/2}$$

RESULTS

Figure 1 shows the outcome of searches and screening: 3821 papers were screened and 4 studies were eligible for inclusion in the synthesis and meta-analysis.

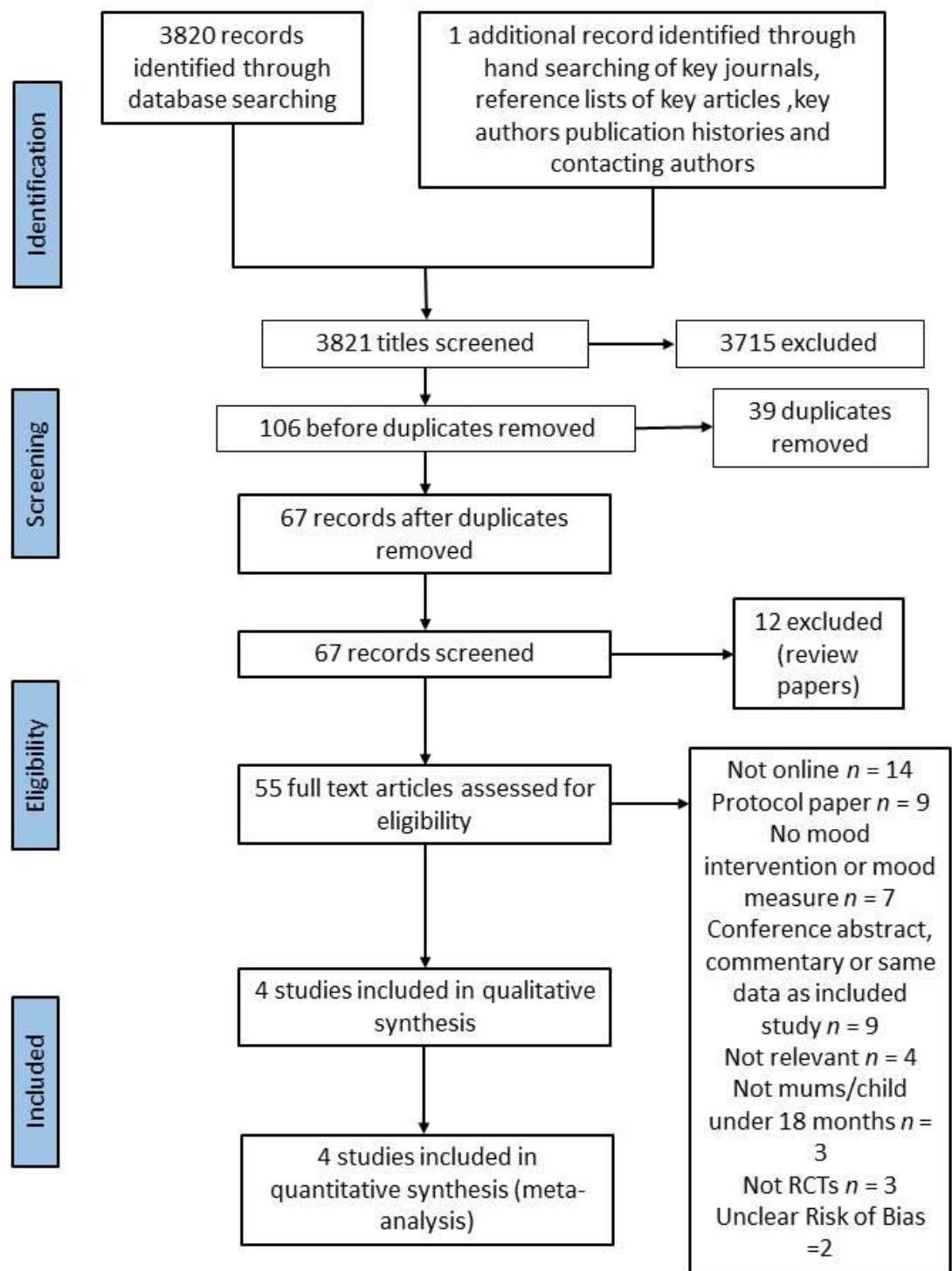


Figure 1: Flow of articles identified, screened and included or excluded.

Risk of bias

Table 1 shows the risk of bias assigned to each domain in the included studies. A thorough breakdown of how these conclusions were arrived at can be found in Appendix 3.1.2 along with a synthesis of risk across domains. No additional significant risk of bias was identified for inclusion in the optional “other” category however methodological and bias issues have been explored further in the discussion.

Table 1: Risk of Bias Summary

| Millgrom 2016 (BDI-II 12 week FU) | O'Mahen 2013 (EPDS 15 week FU) | O'Mahen 2014 (EPDS 17 week FU) | Pugh 2016 (EPDS 7-10 week FU) | |
|-----------------------------------|--------------------------------|--------------------------------|-------------------------------|--|
| + | + | + | + | Random sequence generation (selection bias) |
| + | + | + | + | Allocation concealment (selection bias) |
| - | - | ? | - | Blinding of participants and personnel (performance bias) |
| + | - | + | + | Blinding of outcome assessment (detection bias) |
| + | + | - | ? | Incomplete outcome data (attrition bias) (short term- 7 - 17weeks) |
| + | + | ? | + | Incomplete outcome data (attrition bias) (longer term outcomes 11 weeks - 6months) |
| + | + | + | + | Selective reporting (reporting bias) |

Risk within studies

All 4 studies [26-29] were assigned high or unclear risk of bias for the domain “blinding of participants and personnel” however this would be difficult to implement and ethical issues would need to be considered if this were pursued. The Cochrane Handbook [23] recognises it is unfair to describe all studies of this kind as low quality. These studies are largely free of other bias and can be assumed to have a low overall risk of bias.

Synthesis

Included studies focused on treatment of PND [26-29] and had a low risk of bias. All interventions were described as behavioural or CBT based and these studies were considered suitable for meta-analysis.

Methods

All studies [26-29] evaluated the efficacy of an internet self-help intervention, designed specifically for mothers experiencing symptoms of PND. Studies used the Edinburgh Postnatal Depression Scale (EPDS) [30] to screen or measure depressive symptoms: a cut-off of 9/10 can be used as a screening measure whereas a score of 12/13 is more indicative of the presence of a depressive illness. The EPDS is reported to be the most used tool to assess PND [8] and its use is recommended in national guidelines [9].

Recruitment

A variety of recruitment methods were used. O'Mahen and colleagues [27, 28] recruited via an internet-based parenting website- 'Netmums'. Adverts were placed on the main page, and in the Netmums newsletter. In their 2014 study [28] researchers also recruited via Netmums Postnatal Depression chat room, and their Facebook and Twitter sites. Milgrom et al. [26] used Google AdWords, Facebook and Twitter, and advertised in Health Centres. Pugh et al. [29] used internet advertisements, posters, information cards, media interviews and recruited via doctors and perinatal nurses.

Randomisation

Participants were randomized remotely using a computer programme in all studies. O'Mahen et al. [27, 28] used minimisation to ensure equal distribution of depression severity and current treatment use.

Sample

Table 2 shows participant characteristics. In all studies participants were required to be over 18 years old with a child younger than 1 year old. O'Mahen et al. [27] used an inclusion cut off of 12 or more on the EPDS and in their 2014 study [28]; women were also required to meet ICD-10 criteria for a Major Depressive Disorder (MDD). Milgrom et al. [26] screened women who scored between 11 and 23 on the EPDS, who were not

receiving current treatment for depression (medication or psychological), and denied thoughts of harming oneself. Women meeting these criteria completed the Structured Clinical Interview for DSM disorders (SCID-IV) and were included if they met criteria for a depressive disorder. Pugh and colleagues [29] screened participants using the EPDS; a score of 10 or more was required (mean at screening= 15.96 (SD=3.89), a minority of participants reporting sub-clinical symptoms of depression were included). Participants were excluded if; they were receiving psychotherapy; reported past or present psychotic illness; current suicidal ideation; deliberate self-harm and medication use was required to be stable for at least 1 month.

No differences were reported between baseline characteristics and demographics of participants (Appendix 3.1.3) in the intervention and control arms of studies with the exception of a statistical difference found between participants' work status in O'Mahen's 2013 study [27]: more women in the intervention arm were identified as being on maternity leave, disability leave or being a home maker ($P=.002$). In summary, the majority of participants were married/cohabiting in all studies; educational attainment was similar in three studies (approximately 50% university educated; this was slightly higher in Pugh et al. [29]); 1/3 to 1/2 of participants across studies reported having 1 child with control and intervention groups matched, but more variation was observed between and within studies in relation to participants with 2, 3 or more children.

No data were available in relation to ethnicity in O'Mahen and colleagues 2013 study [27] however; all participants were reported to be UK residents. Approximately 93% of participants in each arm of their following study [28] reported to be white or white British. Milgrom et al. [26] report 96% of participants in their control group and 86% in the intervention group reported being born in Australia. Similarly Pugh et al. [29] stated that 92% of women in the intervention group identified as Caucasian, as did 100% of women in the control group.

Table 2: Baseline characteristics of sample, interventions and outcomes in PND studies.

| | Milgrom et al. 2016 [26] Mum mood booster | O'Mahen et al. 2013 [27] Postnatal internet Behavioural Activation (iBA) | O'Mahen et al. 2014 [28] Netmums Helping with depression | Pugh et al. 2016 [29] TA-iCBT Maternal Depression Online |
|---|--|---|---|--|
| Location | Australia | UK | UK | Canada |
| Sample size intervention group (IG), control group (CG) | n=21, n=22 | n=181, n=162 (Observed analysis) Randomised: n=462, n=448 | n=41, n=42 | n=25, n=24 |
| Age- n, mean (SD), (CG) | n=21, 31.7 (4.6) n=22, 31.5 (4.3) | n=165, 32.3 (4.7) n=134, 32.2 (5.7) | Not available | Not available |
| EPDS n, mean (SD), (CG) | n=21, 16.6 (3.1) n=22, 15.8 (2.8) | n=181, 19.46 (3.81) n=162, 19.44 (3.8) | n=41, 20.24 (3.28) n=42, 21.07 (4.0) | n=25, 14.92 (4.32) n=24, 15.13 (4.06) |
| Attrition rate- (CG) | 3/21, 14% (4/22, 18%) | 281/462, 61% (286/448, 64%) | 4/41, 10% (8/42, 19%) | 6/25, 24% (3/24, 13%) |
| Power achieved | No (n= 50) | No (n=366) | Yes (n=64) | No (n=46) |
| Intervention and support | -6 sequential interactive sessions -a website for partners -low-intensity, manualised weekly telephone coaching delivered by a trainee clinical psychologist, a clinical psychologist or a health psychologist | -11 weekly sessions -weekly email reminders - iBA specific chatroom with parent supporters and HV's -weekly online real time clinics | -12 sessions including 5 core sessions, optional sessions and relapse prevention -meet a local mum feature - weekly, manualised telephone support delivered by mental health workers -access to private chat room moderated by peer supporters | -7 weekly interactive modules -Two trainee clinical psychologists, emailed participants once a week |
| Control | -TAU condition - nominated health professional informed of diagnosis -links to internet resources | -TAU -Access to the general netmums PND chat room moderated by HV and parent supporters | -TAU -Access to the general netmums PND chat room moderated by HV and parent supporters | -Waitlist control -psychoeducation leaflet and list of websites |
| Measures Measure of interest | EPDS used to screen. SCID-IV administered by telephone. Online battery of | EPDS and an "additional set of measures" including a questionnaire about reasons for | EPDS , GAD-7, WASAS, SPS, PBQ, AD-SUS | EPDS , MINI, DASS-21, PSI-SF, WHOQOL-BREF, TAQ, 2 treatment satisfaction questionnaires |

| | | | | |
|--|--|---|--|---|
| | questionnaires: BDI-II , PHQ-9, DASS-21, ATQ, BADS, DAS-7, PSOC Idiosyncratic measures of engagement, and treatment satisfaction | participating. Idiosyncratic measures of feasibility and acceptability | | adapted from the Treatment Satisfaction Questionnaire-Modified (TSQ) and Credibility/Expectancy Questionnaire (CEQ). |
| Follow-up time | 12 week follow-up | 15 week follow-up | 17 week follow-up (6 month follow-up also) | 7-10 week follow-up (T2), (TA-ICBT group T3- 4 weeks following T2) |
| Outcomes | IG- 79% (15/19) no longer met diagnostic criteria for depression (SCID-IV) CG- 18% (4/22) of participants' reported remission. | There was a significant between group difference in those counted as non-depressed (EPDS <12) at 15 weeks favouring the Postnatal-iBA group (n=115/181; 63%) compared to TAU (n=71/162; 43.8%, $P<0.001$). | There was a between group difference in EPDS scores for the observed data analysis at post treatment favouring the NetmumsHWD group ($d=-0.87$ 95% CI -1.32- -0.42) assumed to be calculated using the mean and standard deviation of change. | TA-ICBT- approximately 20% classed as improved, over 62% were recovered. 38% of those in the WLC were classed as recovered, and over 50% exhibited no reliable change. Chi-square analysis showed the difference approached statistical significance: $X^2(1)=2.93$, $P=.80$, Cramer's $V=.026$. |
| Follow-up data used for meta-analysis n, mean (SD), (CG) | 21, 14.5 (12.2) 22, 23 (7.5) | 181, 10.94 (5.57) 162, 14.28 (6.63) | 37, 11.05 (4.71) 34, 14.26 (5.11) | 19, 8.68 (3.8) 21, 12.71 (3.7) |
| Measure | BDI-II | EPDS | EPDS | EPDS |

Note: Adult Service Use Schedule (AD-SUS), Automatic Thoughts Questionnaire (ATQ), Beck Depression Inventory- II (BDI-II), Behavioural Activation for Depression Scale (BADS), Depression, Anxiety and Stress Scales- Short Form (DASS), Dyadic Adjustment Scale (DAS), Edinburgh Postnatal Depression Scale (EPDS), Generalized Anxiety Disorder Scale- 7 (GAD-7), International Neuropsychiatric Interview (MINI), Parenting Sense of Competence Scale (PSOC), Parenting Stress Index-Short Form (PSI-SF), Patient Health Questionnaire-9 (PHQ-9), Postnatal Bonding Questionnaire (PBQ), Structured Clinical Interview for DSM Disorders (SCID-IV), Social Provisions Scale (SPS), Therapeutic Alliance Questionnaire (TAQ), World Health Organization Quality of Life Assessment BREF (WHOQOL-BREF), Work and Social Adjustment Scale (WASAS).

Intervention

Interventions and supports provided in the studies are shown in Table 2. Courses varied in number of modules (range 5-12) and type of support offered (email, online chat

or telephone). All supporters were advised to encourage mothers to engage with the course material and support them with difficulties understanding this and barriers to implementation. Two studies [26, 28] reported manualised guides were used for this. Modules included content such as understanding depression and increasing pleasant activities and mothers were encouraged to complete a module each week, however they often took longer.

Milgrom et al. [26] asked participants in the intervention arm whether additional supports were accessed during the trial and the following were reported: 29% (6/21) reported accessing other supports including- commencing medication, accessing a group treatment, and using self-help books.

Following feedback from the 2013 study [27] where mothers reported feeling overwhelmed by the course, it was amended as shown in Table 2 for the 2014 study [28].

Controls

Comparator groups consisted of a waiting list control (WLC) group and treatment as usual (TAU). In addition Pugh et al. [29] report treatments participants reported receiving in the waiting period including; frequent contact with their GP (58%, 14/24), psychotherapy (33%, 8/24) and medication (25%, 6/24). Participants in Milgrom et al. [26] were also asked for this information: 81% (17/21) reported using one or more sources of support; 19% (4/21) commenced medication and 48% (10/21) reported accessing “other” supports such as the internet, help lines and talking to friends. No information is available about supports mothers may have accessed in O’Mahen et al. [27, 28].

Outcomes

Primary outcome standardised questionnaire measures were completed online in all studies [26-29]. Additionally, trained diagnostic interviewers who were blind to treatment allocation completed the SCID-IV by telephone at 12 week follow-up in Milgrom et al. [26].

Table 2 shows, using observed data, O’Mahen et al. [27] report a statistically significant between-group difference. The authors report a reliable and clinically significant improvement, in the treatment group 61.3% (n=111/181) compared with

41.4% (n=67/162) $P<0.001$ in the control group. When conservatively counting non-responders as depressed the difference still remained in favour of the intervention group.

Additionally, O'Mahen and colleagues [28] report a reliable and clinically significant improvement in depression scores seen in 62.2% (23/37) of the treatment group and 29.4% (10/34) in the control group. This pattern of improved scores and a statistically significant difference between the groups was also observed at 6 month follow-up.

In addition to that shown in Table 2, Milgrom et al. [26] report intention-to-treat (ITT) analysis of data at 12 week follow-up showed a statistically significant between-group difference in the frequency of depressive diagnosis: Yates corrected $\chi^2_1=10.3$, $P=.001$. After controlling for baseline scores, mean depression scores on the BDI-II were significantly lower in the intervention group than in the treatment group $d=-0.83$ (95% CI -1.45, -0.20).

Further to that shown in Table 2 follow-up data for the treatment arm in Pugh et al. [29] showed gains were maintained and participants continued to improve; follow-up 4 weeks post treatment completion (T3) showed statistically significant gains compared with more immediately post-treatment scores (T2) $t(14)=4.13$, $P<0.01$, $d=1.10$.

Given the similarities between studies, the outcomes on depression measures have been pooled and a meta-analysis completed.

Meta-analysis

Data was pooled and a meta-analysis completed using a fixed effects model. Raw data was not available for all studies to allow the calculation of change effect sizes hence follow-up data was used. The outcome is reported in Figure 2 along with measures of heterogeneity and I^2 . Unfortunately due to the small number of studies available, it was not possible to complete further analysis such as a Funnel Plot to statistically assess for publication bias however, grey literature was extensively searched.

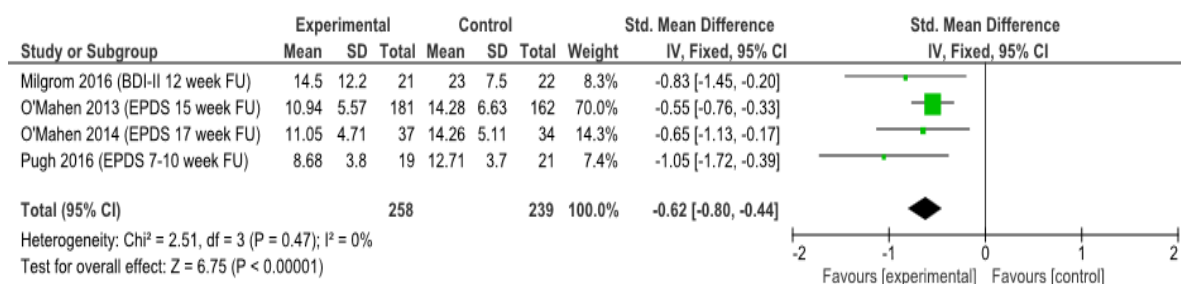


Figure 2: Forest plot showing effect sizes, 95% CI and the pooled effect size of postnatal studies.

Clinical heterogeneity is always present to some degree however; it has been assumed here that it is not present to a degree that would negatively affect the meta-analysis.

Statistical heterogeneity is low and this is shown in the P value- $P=0.47$ which is more than the recommended cut-off of 0.05 suggesting a lack of heterogeneity. This is corroborated by the I^2 statistic- $I^2 = 0\%$ (0-25% classed as low heterogeneity). The combined effect size is $d = -0.62$ (95%CI -0.80, -0.44), reflecting a moderate effect size with all individual and combined effect size confidence intervals firmly favouring the intervention arm of trials.

DISCUSSION

This systematic review aimed to synthesise existing literature on internet CBT based self-help interventions for mothers in the perinatal period. 4 RCTs focused on PND and were judged to have a low risk of bias. A meta-analysis of follow-up data found a moderate effect size: $d = -0.62$ (95%CI -0.80, -0.44) with individual and combined effect size confidence intervals favouring the intervention arm of trials.

PND studies

These studies provide strong evidence that internet CBT can be effective in this population with a low risk of bias observed. The main area of risk identified was difficulty blinding participants and researchers to allocation arm. It is acknowledged this would be difficult to do in studies such as these and studies should not be harshly judged for this; however readers should remain mindful of the suggested influence this can have on results.

In relation to blinding of outcome assessment one study [26] used interviewers who were blind to treatment arm at baseline and follow-up. Given the distant nature of the interaction between participants and researchers in the remaining studies [27-29] (contact was primarily via email) and the use of standardised questionnaire measures it is possible this could have less of an influence on results than perhaps face-to-face therapy may incur. However, it should be noted that all four studies included some kind of support element.

A number of areas were identified that warrant particular consideration with regards to the ability to generalise findings and further areas for research.

Recruitment

The recruitment methods used were primarily aimed at reaching mothers online and this is appropriate given the interventions were delivered online. However, in all studies, participants were largely self-referring volunteers. This can introduce bias and reduce the ability to generalise results. It is likely those who volunteered were able to recognise they were struggling and were motivated to change this. This could lead to inflated intervention outcomes in comparison to what might be seen in the general population. Recruitment from both community and health services should be given further consideration. It is important to note that certain demographics may be favoured or disadvantaged by offering an internet intervention and recruiting primarily via the internet, for example it could favour those who can financially afford internet access.

Sample

Participants' baseline characteristics appeared similar across studies. All studies were conducted in the Western World and where reported it could be observed that few participants were recruited who identified as being part of an ethnic minority group. Given the increased prevalence rate of PND among ethnic populations [3] it is interesting that so few were recruited to these studies. More research is required worldwide and it would be helpful to investigate possible additional barriers such as culture.

The majority of women reported being married or cohabiting. It could be hypothesised that single mothers have less support and could therefore be at increased risk of developing mental health problems, however with less support they could have less time to access resources. Research has explored links between support, partner

status and PND however the outcomes of these remain unclear. Evans et al. [31] report social support from peers is beneficial throughout a woman's pregnancy and can contribute to the prevention and management of PND. However, a large scale longitudinal study published in 2016 [32] looked at the outcomes of 5219 Australian women and reported that whether a woman has a partner or not had no significant bearing on their risk of PND. In addition, their perceived social support appeared to be linked to PND risk at the univariate level, however when analysed at the multivariate level, this result was no longer significant. This indicates that, after controlling for other factors, there was no evidence that social support was associated with PND [32].

Although no study excluded women with a learning disability, no study reported including women with a learning disability. It is therefore unclear how transferrable the outcomes of these studies would be to this population. Although many of the modules included audio and video, they were largely text-based. Where present, telephone support may have helped participants with literacy difficulties.

One of the perceived benefits of internet CBT is its ability to increase access and it is therefore important to ensure that where evidenced based therapies are available they are relevant and accessible for all, inclusive of hard-to-reach populations.

Despite the sample being largely self-selecting, attrition was high- in 3 of the 4 studies [26, 28-29] attrition ranged from 10-24% and in one [27] 61-64%. Attrition rates have been shown to be high in this population [20] and in internet-based courses in general [33], however it has been hypothesised that support would reduce attrition [15] and this has been supported in the studies reviewed here: those with the least amount of support [27] showed the highest attrition. This study also achieved the lowest effect size [27]. A recent large scale pragmatic RCT [34] compared GP delivered TAU to 2 unsupported CCBT packages: Beating the Blues and Mood Gym. Outcomes showed there were no statistically significant differences between outcomes on any of the study arms at any time points with final follow-up completed at 24 months. This further indicates the need for support to increase adherence and efficacy of CCBT interventions.

PND can be a spontaneously remitting condition and it is possible this may account for a proportion of the attrition observed. However, qualitative research [35-36] conducted with participants in two of the included studies [27, 29] showed mothers reported challenges accessing and remaining engaged with the programmes including:

programmes being fast paced or overwhelming, difficulty finding time to log-on and to complete the homework activities, feeling the courses lacked the personalization that would be afforded in face-to-face therapies, feeling hopeless, and previous negative experiences with treatment. Further research would benefit from trying to remove some of these challenges.

Interventions

The internet courses were standardised, however mothers could personalise aspects of their treatment in all of these [26-29]. Supporters in all studies were instructed to focus on course content and helping participants understand and use this. Two studies reported having a manual to guide supporters during sessions [26, 27]. The lack of manuals in the remaining studies makes it difficult to replicate interventions and can make it harder to identify active treatment components.

Pugh et al. [29] offered individualised email support and although high attrition rates were observed (IG- 6/25, 24%, CG-3/24, 13%) the study identified a large effect size $d=-1.05$ (95% CI -1.72, -0.39). Follow-up was completed shortly after course completion between 7 and 10 weeks (T2) and it is possible the shorter follow-up time contributed to the higher effect size. However, participants continued to improve and a significant difference was still observed between scores at T2 and T3 (4 weeks after T2). Interestingly, out of the four included studies, this study recruited participants with the lowest mean scores on the EPDS at baseline and it is possible these women were more able to engage with the course as their symptoms were less severe. Notably NICE guidelines [10] recommend computerised interventions for those with sub-threshold or mild to moderate symptoms rather than those with more severe symptoms. Further research should be completed to identify whether interventions such as this are of most benefit to people with mild to moderate symptoms and whether they can be adapted to be of benefit to people with more severe presentations. Additionally, research to identify the active components of the intervention that have contributed not only to the large effect size but also the continued improvement on completion of the course would be recommended.

TAU is ethically appropriate as it allows participants to access supports and treatments that they need. However, it can mean a large variation in what participants

access. The studies varied in the amount of support details asked of participants in the control arm and this is described in detail in the results section. Only Milgrom et al. [26] reported additional supports accessed by participants in the intervention arm. Accessing these things can confound data, and it is helpful to record them so they can be taken into account when considering treatment effects.

Outcomes

All studies used appropriate statistical analyses e.g. reporting data for both observed and ITT analyses. As expected, stronger effects were seen in observed data, however trends remained present in ITT analyses. It is therefore pertinent that research of a high standard, achieving power be conducted to strengthen the veracity of these results and further develop the evidence base for this treatment.

To date, most follow-up periods have been short; it would be helpful to conduct research over a longer period of time to assess long term outcomes. Furthermore, it would be interesting to know whether women who complete interventions such as these go on to have other children, and if they do how their mood is affected and, if required, how these mothers would seek support.

Meta-analysis

Clear evidence of a treatment effect for the CBT interventions was found with moderate-large effect sizes shown as a result of the interventions trialled. A meta-analysis comparing the follow-up data between the control and intervention arms of the trials found an overall moderate effect size favouring the interventions $d = -0.62$ (95%CI -0.80, -0.44). Given many of the participants in control groups had access to additional supports throughout the control period it is encouraging that effects of this size were observed.

Summary

These are the first published studies that have investigated internet CBT-based interventions to help mothers with symptoms of depression in the postnatal period. Outcomes of these studies suggest that interventions designed specifically for this population can reduce depressive symptomatology. Further confirmatory studies should

be carried out in addition to exploratory studies to identify the active components of interventions and how best to maintain engagement.

This review searched for interventions conducted in the perinatal period however only studies conducted in the postnatal period were found to be of good enough quality to be included. One other RCT was found and this was conducted in the antenatal period with women who were not depressed. This study was judged to have an unclear risk of bias and was therefore excluded from the review. It is noteworthy however that Barrera et al. [32] conducted a fully automated Pilot RCT which used an adapted PND prevention intervention, the Mothers and Babies Course. Participants were recruited online from across the globe and the researchers aimed to describe the sample and assess the efficacy of the course. It is understood no direct contact was made between participants and researchers and no support was offered. Participants were 82.9% Spanish speaking and 71.3% described themselves as Latina. This highlights the global interest across cultures in interventions to prevent mood disorders. The study experienced high attrition (87%), and over half of participants did not log-in to the programme (n=563; 53.72%) and of those who did, approximately 2/3 (n=73; 65.77%) completed only 2 or more (of a possible 6) postpartum follow-up assessments. More research of a higher quality is required to allow for a better understanding of the possible benefits of prevention interventions and treatment interventions for mothers in the antenatal period.

Limitations and implications for future research and clinical practice

The search strategy was wide and inclusive covering both published and grey literature, and researchers who are active in this field were contacted. Despite this only 4 RCTs were identified, showing a paucity of higher quality research in this area. This is surprising given the widespread and long term understanding of the lasting negative implications that PND can contribute to. It is possible given the recent development of internet courses, advances in technology and the shift towards prevention of difficulties, that research in this area is currently being planned or undertaken. The number of protocols identified would indicate this and a larger meta-analysis would be recommended as more literature is published.

Government strategies have placed an emphasis on early intervention and prevention of mental health difficulties. It could be argued that there is nowhere this is

more relevant than in relation to PND as the effects of this can be far reaching [6]. Government strategies have also focussed on increasing access to psychological therapies and as was shown in the introduction, mothers with low mood are a population who are hard to reach and apprehensive of attending services [8]. Internet interventions do not claim to be a replacement for face-to-face therapies, however widely disseminated skills-based interventions could help reduce stigma, increase access and help mothers learn a number of transferrable skills in a cost-effective and timely way.

CONCLUSIONS

An emerging evidence base for the use of internet therapies with mothers with PND, and the role of additional support has been highlighted in this review. More research is required to identify the population this can help most and how to reach them e.g. via health services or directly from the community. A larger well-designed pragmatic trial that can assess delivery robustly is recommended. Active components of the internet interventions should be identified to ensure treatments can be as effective and efficient as possible and which type of support can best supplement this.

A number of areas that would benefit from further research have been identified and in particular the lack of high quality research in relation to prevention of mood disorders in the perinatal period and treating these when they are present in the antenatal period. Early intervention in this way could have lifelong benefits for children and their families and could also reduce the need for mental health services at later stages in life.

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Chapter 2- “Enjoy your baby”, Internet-based CBT for mothers with babies: a feasibility randomised control trial.

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Plain English Summary

Title: “Enjoy your baby”, Internet-based Cognitive Behavioural Therapy (CBT) for mothers with babies: a feasibility randomised control trial.

Background: Around 13% of new mothers experience depression soon after giving birth with Postnatal Depression (PND) representing a global health problem [1]. Untreated PND can affect the development of the relationship between a mother and baby and can have long term outcomes for children. Cognitive Behaviour Therapy (CBT) has been shown to be effective in treating PND. This study piloted a new internet-based CBT treatment for mothers with PND. It is hoped the online nature of the treatment will make it easier for mothers to access than traditional therapy.

Aims:

- To recruit mothers using adverts in the community, online and in a newspaper and to describe the participants who self-refer.
- To trial the delivery of an internet-based life skills course and describe take-up and dropout rates.
- To test the ability to gather data and track participants mood over an 8 week period.
- To identify the feasibility of repeating this project on a larger scale.
- To evaluate what mothers think of the intervention.

Method: Participants were recruited via the community and the internet. This pilot project used a waiting list randomized control design. Mothers had to be over the age of 18 years, have a child less than 18 months old and a score of 5 or more on the PHQ-9, suggesting at least mild depression. Mothers in the immediate access group were given access to the Enjoy Your Baby internet course straight away. This is based on the CBT approach and designed specifically for new mothers. All participants were asked to recomplete the questionnaires at 8 week follow-up and participants in the delayed access arm were then given access to the course. It was not possible to deliver regular, individualised support.

Due to a lack of follow-up data a small discussion group was carried out with four mothers, recruited from a local mums group Facebook page.

Results: Facebook was the most successful method of recruitment and 41 mothers were randomly allocated to either the immediate access (n=21) or delayed access (n=20) control group. There were no differences found between baseline and demographic characteristics of those recruited to either arm. 56% of participants did not complete follow-up measures. Exploratory statistics showed no statistically significant differences between participants who completed follow-up measures and those who did not. Similarly, there were no statistically significant differences between participants who did or did not log-on to the online course. At 8 week follow-up participants in the immediate access arm reported fewer symptoms of PND measured by the EPDS. This difference approached statistical significance.

The discussion group offered recommendations to improve the course, such as making it into an app and changing some of the language used.

Conclusion: Recruitment proved to be a challenge and many mothers did not log-on to the course or complete follow-up measures. A recent study [2] showed without support internet CBT may be ineffective. Adding in regular support to help encourage users to work through the course modules might increase use of the course. It is likely that the lack of use of the package contributed significantly to the findings which suggested little impact on mood.

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SCIENTIFIC ABSTRACT

Background: Postnatal depression is a global health problem with lasting effects on the family. Government policy is focussed on early intervention and increasing access to psychological therapies. There is a growing evidence base for the use of computerised CBT packages and this study investigated the feasibility of a CBT-based self-help internet intervention for new mothers.

Objective: To assess the ability to recruit mothers, deliver an internet course, obtain follow-up data and evaluate what mothers think of the course.

Design: A feasibility randomised control design was used to compare a waiting list control group (delayed access= DA) to the Enjoy Your Baby course (immediate access= IA). Measures were administered at baseline and 8 week follow-up.

Methods: Adverts were placed in the Metro freesheet, on charity web pages, on social media, posters were put up in the community, and leaflets were handed out at mother and baby groups. Participants had to be 18 years old or over with a child less than 18 months old. The IA arm was given access to the course straight away. After 8 weeks all participants were asked to recomplete the original measures and those in the IA arm also gave feedback on the course. Participants in the DA arm were given access after reCompleting the questionnaires.

Due to a lack of follow-up data a small discussion group was conducted.

Intervention: The course contains 4 core modules including helping mothers understand why they feel the way they do and helping them build closeness to their babies. Additional modules, worksheets and homework tasks were available. The DA group were given a list of additional support resources and services, and encouraged to seek additional help if required. All participants received weekly automated emails for 12 weeks as they worked through the course. It was not possible to deliver individualised support.

Results: Despite using a number of recruitment strategies, recruitment was lower and slower than anticipated, and attrition was high. 41 women, primarily recruited via the internet, were randomised (IA n=21, DA n=20). No significant differences were observed between participants in either arm at baseline and no statistically significant differences were identified when the demographics and baseline measures of participants who logged-on to the course were compared to those who did not, or when participants who completed follow-up measures were compared to those who did not. Pre and post intervention scores on the EPDS approached statistical significance ($P=.059$, $r=.444$) favouring the intervention arm.

The discussion group suggested strengths of the course and recommended areas for improvement, including making the course more mobile friendly.

Conclusion: Internet interventions show promise; however it is difficult to recruit mothers, engagement is low and attrition high. A number of recommendations are made and a further pilot or an internal pilot of a larger substantive study should be conducted to confirm recruitment and retention.

Trial ID: ISRCTN90927910.

Key words: postnatal depression, postpartum depression, internet, CBT, cCBT, self-help.

INTRODUCTION

Postnatal depression (PND) prevalence is thought to be around 13% generally and as high as 27% in ethnic minority populations in the UK [1, 2]. It is described as a global health problem [3] due to its effects on the family in the postpartum period and throughout the child's life. Children of mothers who experience PND are at greater risk of experiencing psychological distress, and social and cognitive deficits [4].

Government policy in England [5] and Scotland [6] recognises the importance of early intervention and prevention, and the need for further research and services in these areas. Both developed strategies which aim to put children's needs at the centre of children's services, however they note having a mother free from mental health difficulties is key to children reaching their potential. It is thought supporting families at an early stage can help prevent the development of mental health problems with financial savings in both child and adult mental health services [6]. A report published by the Centre for Mental Health [7] reported on average one case of perinatal depression costs society approximately £74,000, with £23,000 relating to the mother and £51,000 to impacts on the child. A recent systematic review [8] showed internet-based self-help for depression can be cost effective when compared to no treatment. Given the pressures on the National Health Service, both in terms of demands on services and financially, this is encouraging. The IAPT programme in England and Wales [9] and the Matched-Stepped Care system [10] in Scotland aim to increase access for people at the appropriate intensity and at the point of need. Internet interventions have the potential to reduce waiting lists, reduce costs to the NHS and increase quality of life.

New mothers can be reluctant to attend services and report barriers including: difficulties disclosing low mood to their GP or health visitor (HV); concerns they would be perceived negatively; sense of hopelessness about their ability to improve; previous negative experiences of treatment; lack of practical and emotional support; fear of having their baby removed; and difficulty booking appointments with their GP [11, 12]. Mothers also reported the flexibility and anonymity of internet interventions was a benefit as it could fit more easily into their life [12]. Research shows mothers prefer psychological intervention to medication [13]

Lindner and colleagues [14] report on how participants' age influenced how they were recruited to an internet CBT intervention for depression. The oldest group responded to newspaper advertisements (50.12 years old (SD=14.17)) followed by Google

searches (40.26 years (SD=13.46)) and the youngest group of participants were recruited via social media (36.34 years (SD=13.20)). Figures from the Office of National Statistics [15] show most women in the UK give birth between the ages of 26-34 years old suggesting these women would perhaps search for sources of support and information using Google search or via Social Media.

Comparing recruitment methods [16] when trying to recruit a hard to reach population, Arab people, to an internet intervention for anxiety and depression showed 86% (70/81) of participants were recruited via Facebook. This method was calculated to be 2.5 times faster than other strategies: a press release, targeted emailing and advertisements.

An American study [17] recruited pregnant women (mean age 31.0 years, SD=5.1), and described their internet access, and willingness to participate in internet-supported weight-loss interventions delivered by computers or mobile phones. 89% (89/100) had access via a computer, 88% (88/100) via a mobile phone and 86% (86/100) reported access via both. 83% (83/100) reported being fairly or very willing to participate in a computer-based intervention and 49% (49/100) reported being fairly or very willing to participate in a mobile phone based intervention. They calculated women who were older and had additional children would be less likely to be willing to engage in a mobile telephone intervention.

CBT based internet treatments for depression are recommended for use with mild to moderate symptoms in the general adult population [18, 19] and there is emerging evidence for their use with PND [20-23]. The meta-analysis in Chapter 1 showed four studies firmly favoured the intervention with an overall moderate effect size $d = -0.62$ (95%CI -0.80, -0.44). These studies [20-23] recruited between 43 and 910 participants, with the UK studies recruiting 910 [21] and 83 [22] participants using netmums as their sole method of recruitment. However, attrition rates have been high in internet-based interventions and it has been hypothesised that support may reduce this. A systematic review [24] of the impact of guidance on internet-based self-help interventions compared: guided vs. unguided interventions, different doses of guidance, different qualification levels of e-coaches, and synchronous vs. asynchronous communication mode. Mental health difficulties included were: depression, anxiety, social phobia, insomnia and eating disorders, and a variety of guidance methods: email, telephone and forums. Few studies were found in relation to the final three questions and

methodological limitations identified meant it was not possible to draw any robust conclusions from these. Nevertheless, it was clear guided interventions were superior to unguided interventions and this was also shown in an earlier meta-analysis [25]. Chapter 1 showed this trend was also present in internet intervention studies with mothers with PND. All three supported studies obtained follow-up data for more than 80% of participants: 82% [23], 84% [20] and 86% [22] with the majority of participants in the intervention arms accessing the courses and completing follow-up 76% [23], 86% [20] and 90% [22].

In light of this information this study aimed to assess the feasibility of a CBT-based intervention for new mums, delivered via the internet, recruited via the community and particularly the internet.

Enjoy Your Baby

Williams and colleagues developed a number of CBT-based self-help resources for several common mental health difficulties including low mood, anxiety and stress [26]. These can be accessed in a variety of formats such as groups, books and on the internet. The internet-based course used in this study is called Enjoy Your Baby (EYB). The course follows the structure and foundations of previous courses but has been adapted to fit the needs of new mothers specifically.

Aims

- To test the recruitment of new mothers using community based recruitment methods.
- To describe the sample of participants who self-identify as being in need of support.
- To deliver the internet-based life skills course and describe take-up and dropout rates in order to evaluate whether mothers complete the whole or only part of the intervention.
- To test the ability to gather questionnaires and track participants' mood over an 8 week period.
- To identify the feasibility of repeating this project on a larger scale and to contribute to power and sample size calculations for a future substantive RCT.
- To evaluate what mothers think of the intervention.

Hypotheses

1. It is possible to recruit up to 60 participants and gather baseline and follow-up data.
2. More than 50% of participants will complete the four core course modules, with at least 65% data available at follow-up.
3. A reduction in scores on the depression and anxiety measures of participants in the immediate access group will be seen when compared with the delayed access group.
4. There will be minimal or no change to participants' scores on depression and anxiety measures between baseline and gaining access at week 8, in the delayed access group.

METHODS

Quantitative methods

Design

A randomized control design was used to compare a waiting list control group (delayed access arm, DA) to the EYB course. Measures were administered at baseline and 8 week follow-up. The primary outcomes were ability to recruit, deliver the internet course, retain participants and gather follow-up questionnaires. Secondary outcomes were a reduction in reported depressive symptomatology following completion of the course by those in the immediate access (IA) arm.

It was planned that all participants would complete measures at baseline, 8 week follow-up, and 12 week follow-up. However, due to difficulties with recruitment and time constraints it was not possible to complete the 12 week follow-up. Additionally, inclusion criteria were amended to allow mothers with babies up to 18 months old, rather than one year old to be included and mothers were required to have a score of 5 or more on the Patient Health Questionnaire (PHQ-9) [27] at baseline rather than the original cut-off of 10 or more. It had also been hoped participants would be offered either telephone or email support, however the option of telephone support was removed due to the original

supporter being unable to deliver this. Ethical approval was sought for all changes (Appendix 3.2.1) and the ISRCTN was informed of changes to the protocol (Appendix 3.2.2).

Pre-test of Questionnaire burden

Each set of questionnaires were piloted by a minimum of two mothers and a colleague, who were asked to comment on acceptability and burden of completion in particular. Feedback indicated questionnaires were perceived as appropriate in content and length.

Participants

Inclusion criteria- mothers must have a child under 18 months old, be over 18 years old and have a score of 5 or more on the PHQ-9. They should be able to read and understand information presented in English, with access to the internet and the facility to listen to audio commentaries.

Exclusion criteria- women were excluded if they were pregnant, currently engaged in psychological therapy or counselling, or if they reported active suicidal ideation, identified by their response to question nine on the PHQ-9 (“Thoughts that you would be better off dead or of hurting yourself in some way” either “more than half the days” or “nearly every day”). Participants who reported active suicidal ideation were given a list of services that could be contacted for support immediately (including A&E and NHS 24) and redirected to their GP to seek immediate access to mental health services. The researchers also contacted participants GP to inform them.

Sample size

This is a feasibility trial investigating the feasibility and usefulness of conducting a larger study and therefore aimed to inform a power calculation for this. The target for this study was a minimum of 27 participants in each arm [28].

Randomisation

A colleague external to the study used the randomisation function in Microsoft Excel to generate a list of random numbers. Numbers above 0.5 indicated allocation to

the DA arm and below this, to the IA arm. The primary researcher assigned allocation using the predetermined list as participants were recruited and they were informed of their allocation by email. It was not possible for participants or the researcher to be blind to participants' allocation.

Recruitment

Participants were recruited between November 2015 and April 2016. Weekly adverts were placed in the Health section of the Metro newspaper during December 2015 and February-March 2016, and 45 000 digital adverts were delivered on the Metro's sister website www.dailyrecord.co.uk in the "look good, feel good" section. Adverts were placed on Mumsnet and Netmums message boards and a number of charities such as Action on Depression, Bliss and House of Light shared information about the project. Later on in the project posters were displayed in community venues including libraries and community centres across the central Scotland and the researcher attended a number of mother and baby groups and gave short presentations and distributed leaflets. A Facebook page was created to advertise the study and a number of local mothers groups shared the advert via their blogs and on Facebook and Twitter. All adverts (Appendix 3.2.3) directed participants to an online recruitment site (www.lifeskills4mums.com Appendix 3.2.4).

Consent

Informed consent was collected online at recruitment and participants were required to consent to the researchers contacting their GP if there were any risk concerns.

Procedures

Following completion of baseline measures and recruitment, participants were randomised as described. Those in the IA arm were emailed a link to access the course and participants in the DA arm were informed they would be given access in 8 weeks. Following the 8 week period participants in the IA arm were asked to complete the original measures again and to give feedback on the course. Participants in the DA arm were given access on recompletion of the original measures.

Participants who were given access to the course but did not log-on were sent reminders inviting them to do this. Participants who did not complete the follow-up were emailed up to three reminders. Participants who completed follow-up measures were sent a £10 Amazon voucher as a thank you for their time.

All data were collected online using SurveyMonkey. Participants could access the link to complete baseline questionnaires via the recruitment website. Links to follow-up questionnaires were emailed to participants at the appropriate times by CA.

Intervention

The course consisted of four core modules and a number of additional modules. Core modules include helping mothers understand why they felt the way they did, helping them make positive changes, building closeness to their babies and looking at things differently (addressing anxious or negative thinking). Supplementary modules included information on asking for help (assertiveness) and getting to sleep. Mothers could choose to receive weekly automated emails for 12 weeks and the course included a number of worksheets and homework tasks to encourage participants to put what they learned into practice. It was intended initially to offer regular phone based or email support by a research worker. This was not possible, and an abbreviated support was delivered: following their initial log-in participants were emailed an individualised welcome email, from the support account to the email account they registered with and also on the message board of the online course. Participants were aware they could contact both the support and information email accounts. The course is designed so participants can work through the course systematically or choose specific sections in their preferred order, at their own pace (Appendix 3.2.5).

Waiting list control

The DA group were given a list of additional resources and encouraged to seek additional help if required.

Participants in both arms were asked to report any use of additional supports in the 8 week period.

Measures

The primary outcome was to assess the ability to recruit participants, deliver the internet course and to gather evaluations. Demographic data was obtained to allow for a description of the sample. In a future substantive study the primary outcome would be the Edinburgh Postnatal Depression Scale (EPDS) [29].

Secondary Outcome Measures: PHQ-9 [27] a self-report measure of depressive symptoms, Generalized Anxiety Disorder-7 (GAD-7) [30], a self-report measure of generalized anxiety, and the EPDS [29]- a 10 question self-report measure designed for use with mothers of young babies. These measures have been found to be valid and reliable in a number of populations [27] and are widely used in clinical practice and research. The EPDS is the most widely used measure of depressive symptoms in new mothers [31]. NICE guidelines [32] (192) recommend the PHQ-9 and the EPDS as screening measures. A score of 5-9 on the PHQ-9 indicates mild depression whereas a score of 10 or more indicates symptoms consistent with “moderately severe” or “severe depression”.

Statistical Analysis

Descriptive statistics were used to describe the sample demographic details. Exploratory statistics, including Mann-Whitney U and Chi Square analyses were used to investigate the data using SPSS version 21. Confirmatory statistical analysis or an intention to treat protocol is not appropriate given this is a feasibility trial. Descriptive statistics show how participants evaluated the intervention. A power calculation for future studies is reported. Statistical analyses were carried out with advice from a statistician.

Supplementary Qualitative Methods

Due to a lack of follow-up data obtained, a small discussion group was conducted with a separate group of mothers. These mothers were recruited from a local mums group Facebook page. The discussion group was co-facilitated by another DClinPsy trainee and was digitally recorded to enable transcription. Participants were shown screen shots of the website (Appendix 3.2.5) and log-on details to aid discussion. One participant won a £25 Amazon voucher which participating mothers were eligible to be included in the draw for.

Qualitative analysis

Thematic Analysis was used to code and identify themes in the data by following the 7 stages outlined in Braun and Clarke [33]:

1. Transcription.
2. Reading and familiarisation; taking note of items of potential interest.
3. Coding- complete; across entire dataset.
4. Searching for themes.
5. Reviewing themes.
6. Defining and naming themes.
7. Writing – finalising analysis.

Identification of themes was completed independently by CA and a colleague. Themes were compared and a large overlap observed. These were discussed until a final consensus on resulting themes was reached.

Ethical Approval

Ethical approval was obtained via the University of Glasgow Medical and Veterinary and Life Sciences ethics panel (Reference number 200150010: Approval date: 27th October 2015; Appendix 3.2.1). The study was registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN90927910) (Appendix 3.2.2).

RESULTS

Hypothesis 1: It is possible to recruit up to 60 participants and gather baseline and follow-up data.

115 participants accessed the survey monkey link and 67 consented to participate. Mothers were screened for eligibility; 26 excluded and 41 randomized (IA n=21, DA n=20). The majority of participants were recruited via Facebook (IA-n=12, DA-n=9). Remaining participants were recruited from a variety of sources: an email from a charity (n=5), referrals from friends or family (n=4), an advert on a charity website (n=3), the Metro (n=2 directly, n=1 indirectly: participant told about it by a friend), Twitter (n=2), a Google

search (n=1), a leaflet handed out at a group (n=1) and Mumsnet (n=1). An advertisement was also placed on Netmums and although this had over 350 views no participants were recruited from here. Figure 1 shows the flow of participants through the study including reasons for exclusion.

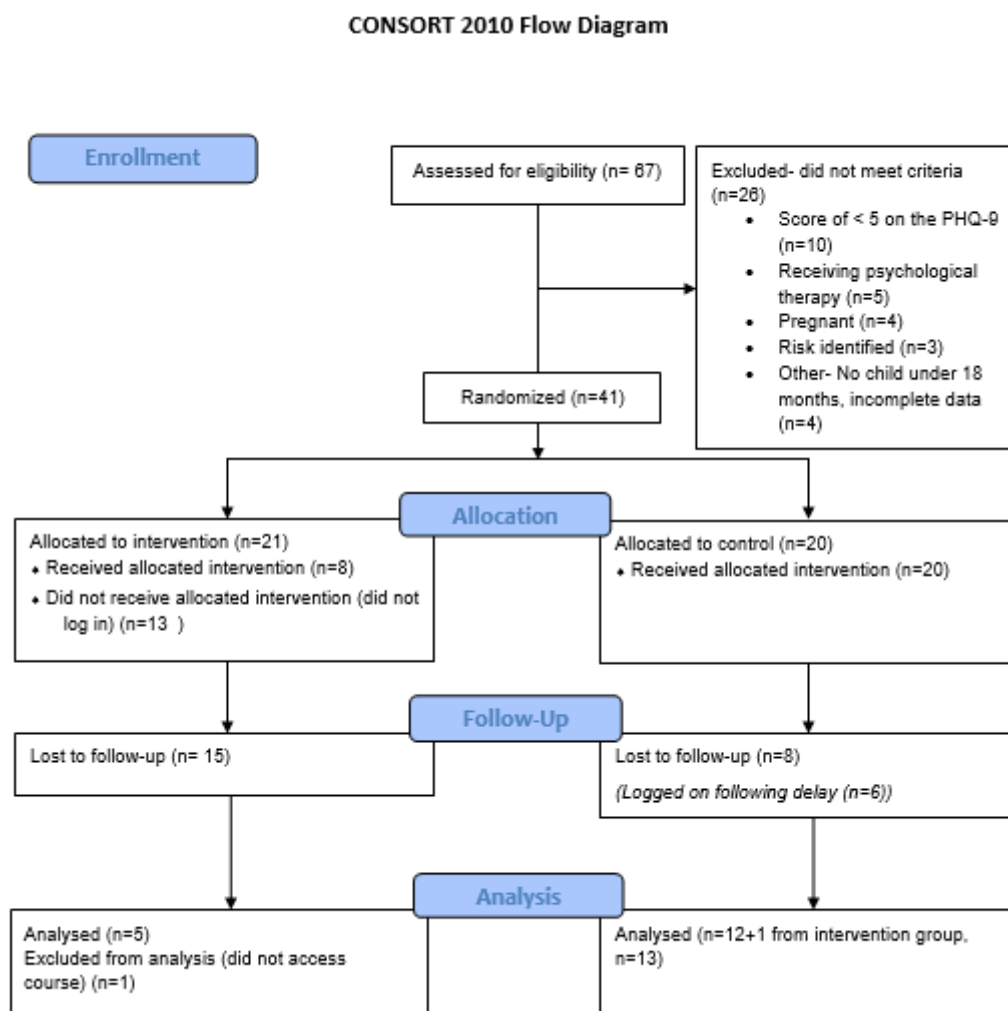


Figure 1: CONSORT diagram showing the flow of participants through the study.

Tables 1 and 2 show there were few differences between baseline demographic and other characteristics of the IA and DA groups evident, suggesting randomisation had been effective. Observation of box plots showed medians and interquartile ranges on the 3 measures depicted parametric data, however due to the small sample size the non-parametric Mann-Whitney U test was used to analyse pre- and post- data between arms. As recommended by the CONSORT statement [34] and a statistician, no statistical tests of between-group differences were conducted on baseline data.

Table 1: Baseline characteristics of participants.

| Characteristics | IA (n=21) | DA (n=20) |
|--|-----------|-----------|
| Married/ Living with partner | 21 | 18 |
| - Single | 0 | 1 |
| - In a relationship but living apart | 0 | 1 |
| Ethnicity- White Scottish/British | 18 | 18 |
| - Ethnicity other (including African and Asian) | 3 | 2 |
| Baby under one year old | 16 | 16 |
| Other children at home | 11 | 7 |
| Pregnancy planned | 19 | 12 |
| Previously sought support | 13 | 13 |
| Currently taking antidepressant medication | 7 | 2 |
| Employment- Full time | 2 | 0 |
| - Part time | 3 | 7 |
| - Self-employment | 1 | 2 |
| - Maternity leave | 11 | 9 |
| - Unemployed | 4 | 2 |
| Highest level of education- Postgraduate degree | 6 | 3 |
| -Undergraduate degree | 9 | 9 |
| - HNC, HND, SVQ (level four or five) or RSA higher diploma or equivalent | 3 | 6 |
| - Higher grade, A levels or equivalent | 3 | 2 |

Table 1 shows 95% (39/41) of participants were married or living with a partner and 88% (36/41) identified as white Scottish or British. 78% (32/41) had a baby under one year old and 66% (27/41) had an undergraduate or postgraduate degree. All participants had some kind of formal qualifications. A minority reported currently taking medication (22%, 9/41).

Table 2: Participants age and scores on the standardised measures at baseline.

| Participants age and measures completed at baseline | IA (n=21) Mdn (IQR) | DA (n=20) Mdn (IQR) |
|---|------------------------|------------------------|
| Age | 30 (28, 34) | 31 (29, 34.75) |
| PHQ-9 | 11 (8.5, 13) | 9 (7, 15.75) |
| GAD-7 | 10 (6, 11.5) | 9 (5.25, 16.75) |
| EPDS | 12 (10.5, 15.5) | 13.5 (10.25, 16.75) |

No differences were observed between participants' median age or scores on the three standardised measures at baseline.

Attrition was high (56%) and exploratory analyses were conducted to explore whether there were any differences between those who logged-on to the course and those who did not (Tables 3 and 4). The same analyses were conducted comparing participants who did and did not complete follow-up measures. No statistically significant differences were observed between those who completed follow-up and those who did not on any of the demographic characteristics or the three measures, tables relating to these analyses can be found in Appendix 3.2.6. Chi Square, Fisher's exact and Mann-Whitney U tests have been used to compare data. Measures of effect sizes are also reported (Pearson's r and Cramer's V).

Table 3: Baseline characteristics of those who logged-on and those who did not.

| Characteristic | Logged-on (n=14) (%) | Did not log- on (n=27) (%) | Significance | Cramer's V |
|--|-------------------------|-------------------------------|--------------|---------------|
| Pregnancy planned | 10 (71.4) | 21 (77.8) | $P=.712$ | .070 |
| - Not planned | 4 (28.6) | 6 (22.2) | | |
| Baby under one year old | 9 (64.3) | 23 (85.2) | $P=.231$ | .239 |
| - Not under one | 5 (35.7) | 4 (14.8) | | |
| Other children | 8 (57.1) | 10 (37) | $P=.322$ | .192 |
| - No other children | 6 (42.9) | 17 (63) | | |
| Highest level of education | | | | |
| - Postgraduate degree | 4 (28.6) | 5 (18.5) | | |
| - Undergraduate degree | 7 (50) | 11 (40.7) | $P=.439$ | .262 |
| - HNC, HND, SVQ (level four or five) or RSA higher diploma or equivalent | 2 (14.3) | 8 (29.6) | | |
| - Higher grade, A levels or equivalent | 1 (7.1) | 3(11.1) | | |
| Employment- Full time | 0 (0) | 2 (7.4) | $P=.194$ | .383 |
| - Part time | 4 (28.6) | 6 (22.2) | | |
| - Self-employed | 2 (14.3) | 1 (3.7) | | |
| - Maternity leave | 8 (57.1) | 12 (44.4) | | |
| - Unemployed | 0 (0) | 6 (22.2) | | |
| Medication use | 2 (14.3) | 7 (25.9) | $P=.692$ | .133 |
| - No medication | 12 (85.7) | 20 (74.1) | | |
| Previous support | 9 (64.3) | 17 (63) | $P=1.00$ | .013 |
| - No previous support | 5 (35.7) | 10 (37) | | |

There were no statistically significant differences between participants who did or did not log-on to the online course. However, 64% (9/14) of participants in the group who did log-on had a baby under one year old in comparison to 85% (23/27) of participants in the group who did not log-on. Similarly 79% (11/14) of participants who logged-on had an undergraduate or postgraduate degree in comparison to 58% (16/27) of participants who did not log-on.

Table 4: Baseline age and scores on measures of those who logged-on and those who did not.

| | Logged-on (n=14) Mdn (IQR) | Did not log-on (n=27) Mdn (IQR) | Z statistic | Significance | Pearson's r |
|-------|-------------------------------|---------------------------------------|----------------|--------------|-------------|
| Age | 32.5 (29, 35) | 30 (28, 34) | .926 | $P=.362$ | .144 |
| PHQ-9 | 10 (7, 15.25) | 10 (7, 13) | -0.28 | $P=.989$ | -.043 |
| GAD-7 | 9.5 (4.75, 13.25) | 10 (6, 16) | -.248 | $P=.817$ | -.039 |
| EPDS | 14 (8.5, 16.25) | 12 (11, 15) | -.566 | $P=.577$ | -.088 |

There were no statistically significant differences between participants' age or scores on baseline measures between participants who did and did not log-on to the course. However, participants who did log-on had a median age 2.5 years older (32.5 years) than those who did not (30 years old).

Hypothesis 2: More than 50% of participants will complete the four core course modules with at least 65% of follow-up data available.

62% (13/21) of participants in the IA arm did not log-on to the course. Six out of a possible eight participants completed follow-up measures, but one of these did not log-on and their data has therefore been treated as if they had been randomised to the DA arm. Following registration, participants automatically received weekly standardised emails for 12 weeks unless they opted not to receive these. Almost all participants in the IA arm were sent a personalised welcome email from the support person (CW) that they could access via the internet course and this was also sent to their registered email address (1 participant did not receive this due to an organisational error). No mother responded or contacted the support team at any time.

Participants were asked to report any additional use of formal and informal supports since beginning the course: one reported commencing therapy and another ending support from a mental health practitioner. Additionally, participants reported using informal supports including friends/other mothers (n=2), a family member (n=1), and other self-help resources (n=2: app and book).

Participants self-reported their use of the course. One accessed the course several times a week, two accessed the course weekly, one monthly, and the final participant reported accessing 2-4 times per month. All five reported completing the Welcome Module and three out of five reported completing all four core modules, the remaining two participants each completed two core modules. Four optional modules were also accessed by participants: “Asking for help”, “Getting sleep”, “What about sex?”, and “How to eat an elephant”.

Participants rated their satisfaction with the internet course as shown in Table 5 (most frequently selected response in bold).

Table 5: Participants reported satisfaction with the EYB Course.

| Statement | Strongly disagree | Slightly disagree | Neither agree nor disagree | Slightly agree | Strongly agree |
|---|-------------------|-------------------|----------------------------|----------------|----------------|
| I found the course helpful | 0 | 1 | 0 | 3 | 1 |
| I found the course easy to access (logging in, getting online etc.) | 0 | 1 | 0 | 2 | 1 |
| I was able to understand the course content | 0 | 0 | 0 | 1 | 4 |
| I learned useful information or skills I have used in my life | 0 | 1 | 1 | 3 | 0 |
| I was able to do the activities suggested by the course | 0 | 1 | 0 | 4 | 0 |
| I found the email/telephone support helpful | 1 | 0 | 3 | 1 | 0 |
| I would recommend the course | 0 | 0 | 2 | 3 | 0 |
| The course met my needs | 0 | 2 | 1 | 2 | 0 |

Feedback was largely positive, with most agreeing the course was helpful, easy to log-on to, content was understandable, they learned skills they have used, were able to do the activities and would recommend the course. Most participants stated they neither agreed nor disagreed the email support was helpful.

Several provided additional comments to the question “*What were the best things about the course?*”

- “Well presented. Email follow-ups reminded you to return. Reminder function was good. Mix of course & work.”
- “Liked the structure and reassurance.”
- “That you had to click often to continue. At first I found this annoying but then realised it was forcing me to keep tuning in to what was being said.”

When asked “*What could be done to improve the course? Was there anything missing?*” mothers reported:

- “Not all content was mobile friendly... (I) felt I didn't get as much as I could out of it.”
- “Make it easier to log-in, I struggled and kept forgetting my details... (I) was often trying to log-in when tired and stressed and impatient.”

Finally mothers were offered the opportunity to leave any additional comments:

- “Sometimes the content seemed to be helpful & understanding, but sometimes it was a bit patronising... and as a result I became quite disengaged.”

Hypothesis 3: A reduction in scores on the depression and anxiety measures of participants in the immediate access group will be seen when compared with the delayed access group.

Hypothesis 4: There will be minimal or no change to participants' scores on depression and anxiety measures between baseline and gaining access at week 8, in the delayed access group.

Participants were deemed lost to follow-up if they did not complete the follow-up measures. Follow-up data is available for n=5 in the intervention arm and n=13 in the control arm, giving a 56% attrition rate.

Secondary outcome measures at 8 week follow-up

Mann-Whitney U calculations compared the change scores between the IA and DA arms (Table 6). No significant differences were found. Power to detect differences between groups has been calculated for each of the measures with an alpha significance level of 0.05. The difference in scores between those in the IA arm and those in the DA arm between baseline and follow-up approached statistical significance on the EPDS ($P=.059$, $r=.444$) with those in the IA arm reporting fewer symptoms of depression at follow-up.

Table 6: Statistical analyses of the difference between change scores in both arms of the study.

| Measure | N | Mdn | IQR | Z Statistic | Significance | Pearson's r | Power |
|-----------|----|-----|------------|----------------|--------------|-------------|-------|
| PHQ-9- DA | 13 | -2 | -3.5, .00 | 1.148 | $P=.289$ | .270 | 0.075 |
| - IA | 5 | -6 | -7.5, -1.5 | | | | |
| GAD-7- DA | 13 | -2 | -5, 1 | 0.198 | $P=.849$ | .046 | 0.239 |
| - IA | 5 | -1 | -7.5, 1 | | | | |
| EPDS- DA | 13 | 1 | -1.5, 3 | 1.883 | $P=.059$ | .444 | 0.237 |
| -IA | 5 | -2 | -7.5, .00 | | | | |

Sample size calculation

Using data obtained in this study a calculation of the required sample size and power to detect a clinically significant change was conducted using GPower 3.1 software powered to detect a between group difference of 5 points which would represent a clinically significant improvement on the EPDS.

Using a between sample t-test, a sample size of 27 participants per arm would be required to have 95% power to detect significant differences where $P<0.05$. The current study suffered a 56% attrition rate. To allow for this in future studies a recruited sample size of 64 participants per arm would be required.

Qualitative Analysis

Four women volunteered for the small discussion group held at a community-based mother and baby group. Three were aged 31-35 and one, 18-24 years old. Three

reported being married or living with a partner (one single parent) and three had a child less than 18 months. All had given birth to their children (no adoption) and one reported having other children. Two mothers had a postgraduate degree and two an HNC or equivalent level qualification. One mother was currently in further education, two on maternity leave and the final participant had part-time employment. All noted English to be their first language and were white Scottish or British. None had a physical or intellectual disability.

Mothers were shown screen shots from the EYB course and “how to log-on” information sheets to aid discussion. All reported being interested in, and could see the possible utility of an internet course such as EYB. All reported accessing the internet frequently; mostly via their mobile phones and using this to seek advice relating to their baby or being a mother.

Using thematic analysis [33] four broad themes were identified: 1. practical accessibility, 2. emotional accessibility, 3. support, and 4. engagement/preferences.

Theme 1: Practical accessibility

Mothers wanted the course to be user friendly, easy to access, not time intensive, not complex, and not requiring much concentration.

- “it’s difficult to make time for doing something but if it’s something that you can just dip in and out of... you know when you’re up at 3 o’clock in the morning...”
- “... the other thing is that I would never get round to logging in each time. So if there’s like a ‘Remember Me’ kind of option? So that when you go on to it you won’t need to log-in each time cause ...you get half way through putting in your email address and I’ve lost motivation...”
- “it would be handy if it was an app.”

Theme 2: Emotional accessibility/ adjustment

Mothers suggested the course would be most helpful in the antenatal stage or a few months following the birth of their baby. Mothers reported they would be too overwhelmed in the initial period following the birth of their child. They viewed the course as something that would help them, but felt at this time they were not thinking about themselves and so would have been unlikely to engage.

- "...it was a few weeks before she arrived... I was like 'I'm gonna read up on all this stuff now' to give me (an) idea about how to cope... So beforehand it's good to have things like this. Cause you're sitting thinking all the time beforehand..."
- "I think the '(Building) Closeness' would be coming before the 'Positive Changes'. Because like, personally when you come home it's such a shock. I mean, I still couldnae believe it for weeks that I had a baby."
- "I'd been breast feeding and to start with it was like every hour... no time to even sleep... Now I'm getting time 'cause she sleeps through the night...maybe from now – this kind of point doing something online would be helpful. But definitely at the first, you know, few months it was difficult getting time there to dae anything."

Theme 3: Support

Mothers described seeking support in a variety of ways, at different times. They wanted to be able to do things for themselves and to appear to be managing well. They reported being reluctant to admit to needing support. Mothers identified their GP, HV and midwives as people they could approach for information and reported feeling reassured by speaking to other mothers and realising they weren't the only one finding things difficult.

Mothers stated they did not like the idea of telephone support as they felt it would be difficult to commit to a time and it was often challenging to have telephone conversations while caring for a child. Mothers added they may find it difficult sharing

personal information with a stranger over the telephone and emailing, online chat or even text messaging might allow them to feel more relaxed and be more likely to fit their lifestyle i.e. being able to access and respond in their own time. Mothers identified their preferred support contact as another mother.

When discussing the course content mothers spoke of finding normalising information reassuring, particularly when feeling overwhelmed and they would like more of this. In addition to the relaxation and “You time” modules mothers stated being able to access a resource that would offer reassurance they were doing the right things, and reminding them they would get through it would be helpful.

Theme 4: Engagement/ preferences

Mothers responded positively to many aspects of the courses such as it being colourful and the content being appropriate- particularly the assertiveness module: “Asking for what you need.” Mother’s reported it would have been useful to have this information in the early months following the arrival of their baby. Mothers doubted the “Getting a good night’s sleep” module could work. One thought the log-on process was obvious and they would have found the sheets explaining how to do this off putting as they were text heavy. Mothers offered advice on the use of some of the language throughout the course:

- “I know why it’s called ‘Enjoy your Baby’ but, I know from a friend that I’ve had that we’ve had a conversation about that page – a lot of people will ask you that question ‘are you enjoying him’ or ‘are you enjoying her’ and actually you’re not always enjoying it in the first few months...”
- “and to add to that, see when I read it? It went ‘Ooh?’.’ Information to get you Back on Track’. I would say if you are struggling, and you’re needing to get back on track – that’s assuming that you’re ‘off track’ – that you’re not doing a good job. You’re already putting all that pressure on yourself. It’s just ‘Back on Track’...you’re kind of feeling that you’re completely off track. Just trying to think – cause you feel guilty all that time anyway, about everything (laughs)”

Mothers also commented on the need for the course to be recommended or endorsed by a reputable source such as an NHS employee e.g. GP, HV, or midwife, and reported concerns in relation to the quality of things found on the internet.

DISCUSSION

Recruitment

Recruitment was lower and slower than anticipated. Metro reports 3.2 million newspaper readers per day and 14.8 million UK web-based users. It has proved to be a good method of recruitment for studies of this kind with different target populations, however it is aimed at commuters and may not reach our target audience with just two participants recruited using this method and another referred after a friend seeing the advert in the Metro.

Mumsnet reports being “the UK’s biggest network for parents, generating over 70 million page views and over 14 million visits per month”. Mums forums have proved successful in other studies [21-22] but adverts could only be placed in threads requiring mothers to actively search for research studies. Netmums report the advert was viewed over 350 times nevertheless no mums were recruited and only one from mumsnet.

The project was advertised on a number of local mums groups social media pages and shared widely with many women recruited from places not directly contacted by the researchers. Facebook was the quickest and most successful recruitment strategy, as seen in other studies with hard to reach populations [16]. Unfortunately, this was the final strategy used and if used initially recruitment may have been more successful.

Adverts purposely avoided using the term PND as it was thought this would deter participants. Mothers were asked to consent for researchers to be able to contact participants GPs if there were any concerns in relation to risk. It is possible mothers did not feel comfortable with this or other aspects of the consent process given 115 people viewed the consent form but only 67 went on to consent. In response to adverts placed on Facebook one member of the public commented they did not feel mothers would answer the measures and demographic questions honestly for fear their GP would be contacted, further suggesting mothers may have found this off-putting.

Mothers also reported they were mindful of the quality of course information and it would be important to think about how the course can be advertised to make mothers aware of the existing evidence suggesting the likely benefits of using it.

This highlights the need to test the feasibility of recruitment to new studies prior to embarking on an RCT. It is likely that our recruitment strategies did not reach as many eligible participants as hoped within our available timeframe. However it must also be considered that a large number did see the advert but were not attracted to a course such as this.

The recruited sample was comparable to that seen in other studies [20-23]. 95% (39/41) were married or living with a partner, 88% (36/41) identified as white Scottish or British, 66% (27/41) had an undergraduate or postgraduate degree and all participants had some kind of formal qualifications. These courses seem to appeal to a specific population but a number of groups are being missed; single mothers, mothers with lower educational attainment and ethnic minorities. In accordance with other research [13] a minority of participants reported currently taking medication for their mental health (22%, 9/41). It was thought this course would appeal most to mothers with children under one year old and 78% (32/41) of participants reported their baby was under one.

Engagement and attrition

Loss to follow-up is common in internet-based research and this study had a 56% attrition rate. There were no statistically significant differences found between participants who completed follow-up and those who did not, nor between those who logged-on to the course and those who did not. However 64%, (9/14) of participants in the group who did log-on had a baby under one year old in comparison to 85% (23/27) of participants in the group who did not log-on. It is possible participants in the group who did log-on had more time. Having someone actively try to help mothers log-on may have helped this. A previous study [17] reported participants were more likely to drop out if they had other children and if mothers were older. This does not appear to have been the case in this study; mothers who logged-on had a median age 2.5 years older (32.5 years) than those who did not, and 63% of mothers who did not log-on had no other children. Participants who logged-on had higher educational attainment; 79% (11/14) of participants who logged-on had an undergraduate or postgraduate degree in comparison to 58% (16/27) of participants who did not log-on.

It must also be considered that on being given access to the course mothers may not have been motivated to log-on due to no longer being interested in the course,

feeling the course would not benefit them or being deterred by the format, for example the impersonal nature.

Lindner and colleagues [14] reported it was possible participants recruited via Facebook could be more likely to drop out due to the passive nature of this recruitment strategy, however 50% of the follow-up data obtained in this study was from participants who responded to Facebook adverts.

Qualitative analyses showed time and ease of use were key factors for use. Participants felt they would use a course like this on their phone. The course currently includes a number of worksheets that can be downloaded and printed out and it would be more user friendly if participants could complete these online. Mothers stated they did not have the time or energy to log-on to something repeatedly and it would be important to consider the possibility of allowing mothers to have the option of a “remember me” function.

Mothers reported they did not think they would have been able to engage in an internet course in the first few months following the birth of their child. Participants’ quotes particularly in theme two, could be clearly mapped to Mercer’s model of Maternal Role Attainment [35] which outlines the four stages mothers pass through during the perinatal period. This should be given further consideration when updating course content.

Active support was not offered to all participants in this study, however of those who it was offered to no mother chose to take this up. Had the support role been conducted as originally designed attrition may have been lower as has been seen in other research [Chapter 1]. The discussion group suggested mothers would find speaking to a stranger on the telephone daunting and impractical. They indicated email or online chat support would be most useful as this could be accessed at a time convenient to them. They reported the support they would find most helpful included normalising and reassurance based content. Mothers said they often felt a sense of not being sure they were doing the right thing or feeling they were failing at everything and they hadn’t realised others had felt this way until after they had passed the worst of this and been able to attend mother and baby groups and to speak with other mothers. A recent study [36] found mothers identified other mothers as being their preferred source of support. The study offered free 24 hour support online to mothers already accessing other

treatments. The support was designed as a “listening service” to mothers. Nine mothers participated in testing the online chat system and it was reviewed favourably.

Research has shown [21, 23] mothers often find weekly modules overwhelming and therefore it was decided in this study to complete the follow-up 8 weeks from baseline to allow mothers more time to complete the four core modules. Length of time between support sessions should also be considered to maximise engagement but prevent mothers from becoming overwhelmed.

Of those who did log-on to the course and gave feedback, this was largely positive. Participants reported using the course fairly regularly and accessing a range of course content. Despite the difficulties with recruitment and engagement this suggests there is value in amending the course in light of the feedback received and completing a further feasibility study including more robust support. However, it should also be considered that online interventions of this nature with this population may not prove popular.

Secondary outcome measures

Although not the primary focus of the pilot, results showing an improvement in participants’ reported symptoms of depression on the EPDS following use of the intervention approached statistical significance ($P=.059$, $r=.444$). This is encouraging for future research where it is the planned primary outcome.

Limitations

The main limitation of this study is the high attrition rate. Although this is not uncommon for studies of this kind it is important to try to reduce this and account for the possibility of this in future studies. The power calculation carried out accounts for a 56% retention rate as was seen in this study and a number of recommendations are suggested to try to reduce attrition.

The lack of individualised support is a further limitation that is likely to have contributed to the high attrition rate. It is recommended that future studies offer consistent individualised support.

The original protocol included a 12 week follow-up unfortunately due to difficulties with recruitment and time constraints it was not possible to complete this. In future it would be useful to have a longer follow-up.

Although the qualitative discussion group gives further insight into mothers preferences it should be noted that not all mothers in the group would have met inclusion criteria for the online course and they did not have the opportunity to use the course independently prior to the group meeting. This would have been more robust had we been able to recruit mothers of this kind. Unfortunately this was not possible due to time constraints. Ideally qualitative interviews would have been conducted with mothers who had been recruited to the feasibility study who fell into one of three categories: 1. Had not logged-on, 2. who did log-on but did not complete follow-up or 3. mothers who logged-on and completed follow-up. This would have allowed for a better understanding of the mothers preferences and what encouraged them engage or deterred them from this.

Recommendations

- Online strategies should be the primary method of recruitment; particularly via mums groups on Facebook.
- Consider managing risk in a different way- rather than contacting participants GPs.
- Adaptations should be made to recruitment or course content to enable single mothers, mothers with lower levels of education and mothers from ethnic minorities to access the course.
- A review of course content should be conducted, including amending some the language and content.
- The course should be updated to allow participants to remain logged-on if they choose and worksheets to be completed directly on mobile telephones.
- Support should be offered to mothers online such as live chat, email or texting- perhaps including support/commentaries from other mums.
- A further pilot or an internal pilot of a larger substantive study should be conducted to confirm recruitment and retention.

Clinical implications

Internet interventions show promise for this population. Chapter 1 and the current study add to research showing the need for improved recruitment strategies and support to improve efficacy of interventions [20-23]. A recently reported large scale pragmatic RCT [37] compared treatment as usual to two unsupported cCBT packages: Beating the Blues and Mood Gym. Outcomes showed there were no statistically significant differences between outcomes on any of the study arms at any time points with final follow-up completed at 24 months. A further trial [38] is comparing two different self-help treatments for OCD: an internet-delivered OCD treatment package; and guided self-help using a book. Both treatments have email or telephone support from a mental health professional. It is hoped this study will provide more robust evidence of efficacy, cost effectiveness and acceptability of self-help treatments for OCD. Given the understanding of the cost of perinatal depression to society [7] the outcomes of the cost-effectiveness of both these studies will be important to consider.

CONCLUSION

This study has shown it was difficult to recruit and engage mothers in an internet intervention for mothers with low mood following the birth of a baby. It is possible that this could reflect a lack of interest in internet interventions for this population. Recruitment and retention may be improved following modifications to the course content in response to mothers feedback (e.g. changes to language used and addition of more normalising and more supportive content). Additionally recruiting from what could be termed as more “trustworthy” sources and adding evidence supporting research such as this to participant information sheets may also improve this. Consistent support may increase course use and it is possible increased use in itself would improve engagement and participants outcomes. Participants in this study preferred the concept of email or online chat support. A further pilot or an internal pilot of a larger substantive study should be conducted to confirm recruitment and retention. Ongoing research into effectiveness, cost effectiveness and long term outcomes of internet therapies is required.

Conflict of Interest

Professor Chris Williams is author of a range of CBT-based resources that address anxiety, depression and other disorders. These are available commercially as books, cCBT products, and classes. He receives royalty, and is shareholder and director of a company that commercialises these resources

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Chapter 3: Appendices

Appendix 3.1.1: Author Guidelines for Journal of Medical Internet Research (JMIR)

For general information about the structure and content of a biomedical manuscript, authors should become familiar (skim through) the ICMJE Uniform Requirements for Manuscripts before reading the specific instructions for JMIR authors below.

The Journal of Medical Internet Research (JMIR) and its sister journals are innovative, international, peer-reviewed medical journals that aim to publish articles relevant for medical professionals, system developers, and system users alike.

We accept the following:

- original papers (see format below)
- short papers (original article < 1500 words)
- viewpoints (opinion and discussion papers)
- consensus papers
- reviews
- tutorials
- case reports
- policy papers, proposals
- commentaries
- book/software reviews
- research protocols and grant proposals (now published in our new spin-off journal JMIR Research Protocols)
- letter to the editor (ONLY in response to a previous publication in JMIR, which must be cited as first reference)

We have no rigorous space restrictions for any of these papers, except for the short paper. However, we urge authors to be concise. A typical paper contains between 3000 and 6000 words.

Acknowledgements, Conflicts of Interest

A description of sources of funding, financial disclosure and the role of sponsors must be included in the **Acknowledgements** section of the manuscript. This description should include the involvement, if any, in review and approval of the manuscript for publication and the role of sponsors.

In addition, authors must disclose in a **Conflicts of Interest** section if they have personal financial interests related to the subject matters discussed in the manuscript.



Format for Original Papers

Papers should be written in accordance with the American Medical Association Manual of Style: A Guide for Authors and Editors. 9th ed. Baltimore, Md: Williams & Wilkins; 1998.

The following format ("**IMRAD Format**") must be used for the paper:



- Abstract (not exceeding 450 words for structured abstracts, see [abstract format](#) below)
- Keywords - see [Keywords](#)
- Introduction (eg, theory, hypotheses, prior work)
- Methods (eg with the subheadings "Recruitment", "Statistical Analysis", etc.)
- Results (eg, user statistics, evaluation outcomes). If your study consists of different stages/parts, subheadings in this section should mirror subheadings in the methods section to describe these parts.
- Discussion (eg, with the subheadings "Principal Results", "Limitations", "Comparison with Prior Work", "Conclusions")
- Acknowledgements
- Conflicts of Interest
- [optional] Multimedia Appendix of supplementary files (eg, a PowerPoint presentation of a conference talk about the study, additional screenshots of a website, mpeg/Quicktime video or audio files, or Excel, Access, SAS, or SPSS files containing original data) - see [Multimedia Appendix](#)
- References - see [References](#)
- Abbreviations - see [Abbreviations](#)

Please use subheadings within the main "Introduction," "Methods," "Results," and "Discussion" sections. For example, if you describe three different methods, use three subheadings within the "Methods" section. Also, use matching subheadings in the "Results" section if you report the results from each of the described methods.

Randomized controlled trials (RCTs) are highly welcome and should be reported in accordance with the  [CONSORT](#) statement. A  [diagram](#) illustrating the flow of participants through the trial is required.

NEW JMIR is now pilot-testing a **[CONSORT-EHEALTH checklist](http://www.jmir.org/ojs/public/journals/1/CONSORT-EHEALTH-v1-6.pdf)** - please download the checklist from <http://www.jmir.org/ojs/public/journals/1/CONSORT-EHEALTH-v1-6.pdf>. Although this is primarily intended for randomized trials, the section of the checklist describing how an intervention should be reported is also relevant for manuscripts with other evaluation designs.

A CONSORT-flow diagram and attrition diagram are also strongly recommended (as figures).

In accordance with ICMJE recommendations, **RCTs must have been registered in a WHO accredited trial registry**. Please mention the ClinicalTrials.gov registration identifier, the  [International Standard Randomized Controlled Trial Number \(ISRCTN\)](#), or a comparable trial identifier at the end of the abstract ("Trial Registration: ClinicalTrials.gov NCT123456"), as well as when you first mention the trial in the manuscript. **Meta-analyses and systematic reviews** are also highly welcome and should be reported in accordance with the  [QUORUM](#) statement.

Abstract Format

The abstract for an original paper, systematic review, or consensus paper must not exceed 450 words and must be **structured**, using the following sections:

- Background
- Objective
- Methods

- Results (make sure to include relevant statistics here, such as sample sizes, response rates, P-values or Confidence Intervals. Do not just say "there were differences between the groups")
- Conclusions
- (Trial ID number, e.g. ISRCTN, for RCTs)

Keywords

Below the abstract, authors should provide 3 to 10 keywords or short phrases that will assist indexers in cross-indexing the article and that may be published with the abstract. Terms from the medical subject headings (MeSH) list of Index Medicus should be used (see <http://www.nlm.nih.gov/mesh/MBrowser.html>). As well, keywords from [ACM's Computing Classification System](#) may be used if suitable MeSH terms are not available.

References

- Include a **reference list** (numbered 1., 2., 3. etc.) at the end of the paper. While in-text references are in square brackets [1], the bibliography at the end of the text must be numbered 1., 2., 3. etc (no square brackets).
- Cite **only published or accepted** ("in print") work as reference. *Submitted* papers (not yet accepted for publication), documents not widely available (personal emails, letters), or oral communications (unless they are published as abstract) should *not be cited as reference*, but instead must be cited in the main body of text as "personal communication by NAME, DATE". Obtain the permission of the communicator to quote his communication.
- New (12/2010): **For Medline indexed references, we now ask that you append the PubMed Identifier (PMID) after each reference**, e.g. "PMID:1234567" (where 1234567 is the pubmed identifier) at the end of a reference. Alternatively (as per our old instructions) you could append a [\[Medline\]](#) link after each reference, linking to the PubMed abstract of the article you are citing.
- **If references are not listed in PubMed, please try to identify the DOI** (digital object identifier) and add the DOI at the end of the reference (e.g. doi:10.1136/bmj.331.7529.1391).
- **For books, please add the ISBN, if known** (no blanks). See e.g. <http://isbndb.com/>

- Number references in the order they appear in the text; do not alphabetize.
- Identify references within the body of the paper with Arabic numerals **enclosed in square brackets** (eg, [1,2]). Do **not** use superscripts.
- References must comply with JMIR style (see examples below).
- **Websites and Web articles (URLs)** should be cited as "webcited[®]" references *in the reference section at the end of the manuscript* - do **not** include links to websites in the text.
- Use Medline abbreviations for journal titles (see PubMed [Journal Browser](#)).

Abbreviations

All acronyms/abbreviations (including common ones such as WWW and HTML) must be explained in parenthesis after their first occurrence.

Multimedia Appendix

We strongly encourage to append multimedia appendices, for example research instruments (questionnaires), movie files including screencasts, a Powerpoint file containing additional screenshots or slides from a talk about the study, a Word, RTF, or PDF document showing the original instrument(s) used, a video, or the original data (SAS/SPSS files, Excel files, Access Db files etc.). Do not include copyrighted material unless you obtained written permission from the copyright holder, which should be faxed to the editorial office in case of acceptance together with your Publication Agreement form.

Figures and Tables

Include all figures and tables in the manuscript at the location where they should appear in the final manuscript.

Screenshots of the intervention/website as a figure or a movie file of the intervention (as Multimedia Appendix, see above) are highly encouraged.

When preparing **tables**, please make sure that for each row you create a new table row, rather than writing multiple rows into one cell.

It is technically not possible to generate different table headers for the same column in the course of the same table (e.g. switching from "%" to "mean") - the original table header will be automatically repeated on new pages. If the meaning of the column changes, then this constitutes a new table with a separate label and caption. If you report different metrics for different kinds of data (e.g. % for dichotomous outcomes, means and SD for continuous outcomes), write "(mean, SD)" or "(%)" after the category headings, or find alternative ways to present the information (e.g. footnotes).

Use portrait format and 10-12 pt fonts for tables. Do *not* use landscape paper formats for tables or smaller fonts to squeeze more information (more columns) into a table. **Footnotes for tables** must always be a-z (superscript). Do not use symbols such as * or ** (AMA styleguide has recently been revised to that effect - older JMIR articles still use symbols).

Important Notes on Reporting *P* values

The actual *P* value should be expressed ($P = .04$) rather than expressing a statement of inequality ($P < .05$), unless $P < .001$. The *P* value should be expressed to 2 digits whether or not it is significant. When rounding, 3 digits is acceptable if rounding would change the significance of a value (eg, $P = .049$ rounded to .05). If $P < .01$, it should be expressed to 3 digits.

The traditional reporting of *P* values (indicating only that $P < 0.05$) simply indicated whether the results were "statistically significant" or not. But *P* values of 0.051 and 0.049 should be interpreted similarly despite the fact that the 0.051 is greater than 0.05 and is therefore not "significant" and that the 0.049 is less than 0.05 and thus is "significant." Reporting actual *P* values avoids this problem of interpretation. *P* values should not be listed as not significant (NS) since, for meta-analysis, the actual values are important and not providing exact *P* values is a form of incomplete reporting.

Do not use 0 before the decimal point for statistical values *P*, alpha, and beta because they cannot equal 1. For some statistical values (eg, kappa) even if they cannot ever equal 1, use 0 if they are used infrequently.

***P* is always italicized and capitalized.**

Appendix 3.1.2: Cochrane Risk of Bias tables and synthesis for included studies

Table 1: Pugh et al. 2016

| Entry | Judgement | Support for judgement |
|---|-----------|--|
| Random sequence generation (selection bias) | Low risk | Quote: Eligible and willing participants were individually randomized (allocation 1:1)... blocked randomization. |
| Allocation concealment (selection bias) | Low risk | Quote: Random allocation was conducted via an internet computer program by a researcher who was not involved in the study. |
| Blinding of participants and personnel (performance bias) | High risk | Quote: ...it was not possible for the study therapists and participants to be blind to the treatment assignment. |
| Blinding of outcome assessment (detection bias) (patient-reported outcomes) | Low risk | Quote: Post intervention/delay period measures were administered to all participants over a secure internet website. Comment: Due to the detached nature of this method the reviewers consider that this method is likely to have a low risk of bias. |
| Incomplete outcome data addressed (attrition bias) (Short-term outcomes (7-10 weeks)) | Low risk | Quote: Attrition rates for TA-ICBT and WLC were 16% (n=4) and 12.5% (n=3) respectively between T1 and T2. |
| Incomplete outcome data (attrition bias) (Longer-term outcomes (4 weeks after T2)) | Low risk | Quote: Attrition rates for the TA-ICBT group between T2 and T3 was 28.5% (n=5). Comment: It is unclear whether the researchers used other methods to try to obtain this data if they did not respond to the initial email. |
| Selective reporting (reporting bias) | Low risk | Comment: All outcome measures reported were analysed. |

Table 2: O'Mahen et al. 2013

| Entry | Judgement | Support for judgement |
|---|--------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: We randomised consenting participants... we used minimisation to ensure equal allocation across conditions by severity of depression and whether participants were currently receiving treatment (medical or psychological). |
| Allocation concealment (selection bias) | Low risk | Quote: ...remotely using a computer-generated code to ensure allocation concealment. |
| Blinding of | Unclear risk | The study did not directly address this |

| | | |
|---|--------------|---|
| participants and personnel (performance bias) | | outcome. Comment: It would be difficult to blind participants and personnel in this study. |
| Blinding of outcome assessment (detection bias) (patient-reported outcomes) | Low risk | Quote: Women responded to the EPDS at sign-up and at 15 week follow-up. Women who did not respond to the 15 week follow-up received an email reminder 2 weeks later. Attempts were made to contact non-responders via telephone. Comment: Participants were asked to complete measures via email and had no face to face contact with researchers. |
| Incomplete outcome data addressed (attrition bias) (Short-term outcomes (15 weeks)) | High risk | Quote: Attrition rates in this trial were high. Thirty-nine percent (343/910) of women completed the 15-week EPDS. |
| Incomplete outcome data (attrition bias) (Longer-term outcomes) | Unclear risk | Comment: Not applicable- this was not addressed in this study. |
| Selective reporting (reporting bias) | Low risk | Comment: The authors report on the measures described. |

Table 3: O'Mahen et al. 2014

| Entry | Judgement | Support for judgement |
|---|-----------|--|
| Random sequence generation (selection bias) | Low risk | Quote: Eligible and consenting women were randomized to receive either NetmumsHWD or TAU, minimized on depression severity (EPDS ≥ 13) and whether or not they were receiving pharmacological treatment. |
| Allocation concealment (selection bias) | Low risk | Quote: The minimization algorithm included a stochastic element to inform the allocation bias and was administered remotely using a computer-generated code to ensure concealment. |
| Blinding of participants and personnel (performance bias) | High risk | Quote: ...eligible women were sent an electronic link to a webpage where they could learn their randomization assignment. Comment: It would be difficult to blind participants and personnel in this study. |
| Blinding of outcome assessment (detection bias) (patient-reported outcomes) | High risk | Quote: Data were collected online and via telephone. Comment: It is possible that telephone |

| | | |
|---|----------|---|
| | | communication in particular could have influenced participants to respond in a more favourable manner. |
| Incomplete outcome data addressed (attrition bias) (Short-term outcomes (17 weeks)) | Low risk | Quote: ... 37/41 (90%) women in the NetmumsHWD condition and by 34/42 (81%) women in the TAU. Comment: Acceptable level of attrition given the follow-up time and study type. |
| Incomplete outcome data (attrition bias) (Longer-term outcomes (6 months)) | Low risk | Quote: A 6-month follow-up was completed by 31/41 (76%) women in the NetmumsHWD group and 28/41 (68%) women in the TAU group... Comment: Attrition is higher however given the length of follow-up time and in comparison to other studies of this kind this has been rated as low risk. |
| Selective reporting (reporting bias) | Low risk | Comment: The study protocol is not available; however measures identified appear to have been reported. |

Table 4: Milgrom et al. 2016

| Entry | Judgement | Support for judgement |
|--|--------------|---|
| Random sequence generation (selection bias) | Low risk | Quote: The randomization procedure used a 1:1 allocation ratio and a pre-generated permuted blocks allocation schedule... |
| Allocation concealment (selection bias) | Low risk | Quote: ... with the sequence concealed from the researchers... |
| Blinding of participants and personnel (performance bias) | High risk | Quote: Treatment allocation to condition was revealed in a phone call... Given the nature of the intervention, participants could not be blinded to treatment beyond the point of allocation. |
| Blinding of outcome assessment (detection bias) (patient-reported outcomes) | Low risk | Quote: Diagnostic interviewers were blinded to the treatment allocation at the 12-week time point. |
| Incomplete outcome data addressed (attrition bias) (Short-term outcomes (9 weeks)) | Unclear risk | Comment: DASS Anxiety and DASS Stress measures were administered at 9 weeks. These were completed by 19/21 participants in the treatment arm and 21/22 participants in the control arm. It is not reported why the EPDS was not re-administered at this time. |
| Incomplete outcome data (attrition bias) (Longer-term) | Low risk | Quote: ...two women in the MumMoodBooster condition failed to complete the online assessment |

| | | |
|--------------------------------------|----------|--|
| outcomes (12 weeks)) | | questionnaires and telephone diagnostic interviews (all women in TAU completed the 12-week assessments). |
| Selective reporting (reporting bias) | Low risk | Comment: All identified measures have been reported on. |

Risk of Bias Synthesis

Each domain is reviewed across studies to enable a deeper understanding of bias. See Figure 1 in the main text for a visual representation.

Bias across domains

Selection bias

- Random sequence generation

All of the studies gave an account of their randomization process suggesting a low risk of bias.

-Allocation concealment

4 studies [26-29] gave a description of allocation procedure- usually computer generated and accessed by someone not directly attached to the project. These were assumed to have a low risk of bias.

Performance bias

-Blinding of participants and personnel

3 studies [26, 28-29] addressed this issue directly and stated that it was not possible to blind participants and personnel and had a high risk of bias. The remaining study [27] was assigned unclear risk of bias as it did not refer to this directly.

-Blinding of outcome assessment

The Milgrom et al. [26] study was the only study to report assessors were blind to treatment group at follow-up which suggests low risk of bias. O'Mahen et al. [28] report data were collected either online or by telephone, the use of the telephone in this scenario suggests there is the possibility of high risk of bias. The remaining studies [27, 29] suggest their follow up data were collected online. Due to the detached nature of this

method of data collection and standardised assessment tools to collect the primary outcome data this has been judged as a low risk of bias.

Incomplete outcome data (attrition bias)

- (short-term [7- 17 weeks])

Milgrom et al. [26] collected short-term follow-up data on the DASS Stress and DASS Anxiety but not on the EPDS and this has therefore been assigned unclear risk of bias. O'Mahen et al. [27] collected follow-up data at 15 weeks however attrition was high and this has therefore been recorded as high risk of bias. The remaining 2 studies collected data at a range of follow-up points: 7-10 weeks [29] and 17 weeks [28]. Both reported lower attrition and were categorised as low risk of bias.

- (long-term [11weeks- 6months])

O'Mahen et al. [27] did not collect any long term follow-up data and was therefore assigned unclear risk of bias. O'Mahen et al. [28], Milgrom et al. [26] and Pugh et al. [29] were viewed to have a low risk of bias. Long-term follow-up data ranged from 11 weeks to 6 months.

Selective reporting- reporting bias

There were no protocols available for any of the studies included in this review. O'Mahen et al. [27-28], Milgrom et al. [26] and Pugh et al. [29] all appear to have reported results on identified measures and have therefore been classed as low risk of bias.

Risk within studies

The included studies [26-29] were assigned high or unclear risk of bias for blinding however it is noted that this would be difficult to implement and a number of ethical issues would need to be considered if this were to be pursued. The Cochrane Handbook [23] recognises that it is unfair to describe all studies of this kind as low quality. These studies are largely free of bias and can be assumed to have a low overall risk of bias.

Appendix 3.1.3: Characteristics of participants in included studies.

Table 1. Baseline and demographic characteristics of participants in included studies.

| Baseline characteristic | Milgrom et al. 2016 | O'Mahen et al. 2013 | O'Mahen et al. 2014 | Pugh et al. 2016 |
|--|---------------------|---------------------|---------------------|------------------|
| Age (n, mean and (SD)) Intervention group (IG) | 21, 31.7 (4.6) | 165, 32.3 (4.7) | N/A | N/A |
| Age (n, mean and (SD)) Control group (CG) | 22, 31.5 (4.3) | 134, 32.2 (5.7) | N/A | N/A |
| EPDS at baseline (n, mean and (SD) IG | 21, 16.6 (3.1) | 181, 19.46 (3.81) | 41, 20.24 (3.28) | 25, 14.92 (4.32) |
| EPDS at baseline (n, mean and (SD) CG | 22, 15.8 (2.8) | 162, 19.44 (3.8) | 42, 21.07 (4.0) | 24, 15.13 (4.06) |
| Participants married/ cohabiting n (%), IG | 18 (86) | 123 (91.8) | 38 (92.6) | 22 (92) |
| Participants married/ cohabiting n (%), CG | 20 (91) | 157 (95.2) | 38 (90.5) | 18 (78) |
| Participants with an undergraduate university degree or higher n (%), IG | 10 (48) | 80 (49.1) | 23 (56.1) | 14 (59) |
| Participants with an undergraduate university degree or higher n (%), CG | 11 (50) | 52 (39.7) | 21 (50) | 16 (70) |
| Participants with 1 child n (%), IG | 7 (33) | 69 (41.8) | 19 (46.3) | 11 (46) |
| Participants with 1 child n (%), CG | 7 (32) | 53 (39.6) | 16 (38.1) | 11 (48) |
| Participants with 2 children n (%), IG | 7 (33) | 71 (43.0) | 18 (43.9) | 8 (33) |
| Participants with 2 children n (%), CG | 11 (50) | 58 (43.3) | 16 (38.1) | 11 (48) |
| Participants with 3 or more children n (%), IG | 7 (33) | 25 (15.2) | 4 (10) | 6 (25) |
| Participants with 3 or more children n (%), CG | 4 (18) | 23 (17.1) | 10 (23.8) | 1 (4) |

Appendix 3.2.1: Copy of ethical approval and amendment letters



27th October 2015

Dear Claire Adey and Professor Chris Williams

MVLS College Ethics Committee

Project Title: Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial

Project No: 200150010

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: July 2016
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research:
(http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'A Rankin'.

Prof. Andrew C. Rankin

Deputy Chair, College Ethics Committee

Andrew C. Rankin
Professor of Medical Cardiology
BHF Glasgow Cardiovascular Research Centre
College of Medical, Veterinary & Life Sciences

University of Glasgow, G12 8TA

Tel: 0141 211 4833

Email: andrew.rankin@glasgow.ac.uk

7th December 2015

Dear Claire Adey and Professor Chris Williams

MVLS College Ethics Committee

Project Title: Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial

Project No: 200150010

The College Ethics Committee has reviewed your application for amendments and has agreed that there is no objection on ethical grounds to the proposal to:

- include mothers with babies under 18 months rather than under one year only.
- change the required score on the PHQ-9 from 10 or more to 5 or more.
- only offer support online and via email rather than having the choice of email or telephone.

These approvals are subject to the following conditions:

- The research should be carried out only on the sites and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely



Prof. Andrew C. Rankin

Deputy Chair, College Ethics Committee

Andrew C. Rankin
Professor of Medical Cardiology
BHF Glasgow Cardiovascular Research Centre
College of Medical, Veterinary & Life Sciences

University of Glasgow, G12 8TA

Tel: 0141 330 2895

e-mail: andrew.rankin@glasgow.ac.uk

Dear Claire Adey and Professor Chris Williams

MVLS College Ethics Committee

Project Title: Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial

Project No: 200150010

The College Ethics Committee has reviewed your application for amendments and has agreed that there is no objection on ethical grounds to the proposal to:

- allow Carrie-Ann McClay to contact mothers by telephone to welcome them to project and to offer general guidance and support about the use of the online course.
- set up a facebook page/ facebook account (using the email address c.adey.1@research.gla.ac.uk if required) to advertise the research project, direct people to the project website and to join other pages and groups such as closed mums groups to share information about the project.
- run focus groups with mums to ask primarily about methods and barriers to recruitment and also to show them the online course and ask what they think of it.
- increase the “thank you” offered to participants for giving their time and effort, from a £5 Amazon voucher to a £10 Amazon voucher per participant.
- offer a “prize draw” for a £25 Amazon voucher to one focus group participant.

These approvals are subject to the following conditions:

- The research should be carried out only on the sites and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely



Prof. Andrew C. Rankin
Deputy Chair, College Ethics Committee

Andrew C. Rankin
Professor of Medical Cardiology
BHF Glasgow Cardiovascular Research Centre
College of Medical, Veterinary & Life Sciences

University of Glasgow, G12 8TA

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e-mail: andrew.rankin@glasgow.ac.uk

Appendix 3.2.2: ISRCTN Protocol

ISRCTN90927910 DOI 10.1186/ISRCTN90927910

Enjoy your baby, life skills for mums with new babies: a pilot randomised control trial

Condition category

Mental and Behavioural Disorders

Date applied

05/11/2015

Date assigned

06/11/2015

Last edited

31/03/2016

Prospective/Retrospective

Prospectively registered

Overall trial status

Ongoing

Recruitment status

No longer recruiting

Plain English Summary

Background and study aims

Around 13% of new mothers experience significant and sustained depression soon after giving birth, this is referred to as postnatal depression (PND). PND has been described as a global public health problem not just because of the effect this has on mothers, but also on the mothers' partners and their babies. Untreated PND can affect the developing relationship and attachment between mother and baby and this can have long term consequences for the children e.g. being at higher risk of developing depression themselves. Cognitive behavioural therapy (CBT) has been shown to be effective in treating PND. This study aims to test a CBT-based online treatment for mothers with low mood. It is hoped that the online nature of the treatment will make it easier for new mothers to access than traditional, clinic based face-to-face therapy.

Who can participate?

Women over the age of 18 with a baby less than 18 months old that are experiencing mild to moderate symptoms of low mood, stress and anxiety.

What does the study involve?

Potential participants are asked to complete short questionnaires which ask about their mood as well as personal information such as age, school history and work status. This information is used to select suitable participants. Selected participants are randomly allocated to one of two groups. Those in group 1 (immediate access group) are given access to the online course. Those in group 2 (delayed access group) are told that they will be given access to the online course later. The course has been developed to help mums learn a number of practical life skills, such as problem solving, overcoming low confidence, boosting mood with the aim of improving mild to moderate feelings of low mood and stress. The course runs for a period of 8 weeks. All participants (from both groups) are asked to complete questionnaires before they begin the study and again after the 8 week study period.

What are the possible benefits and risks of participating?

It is hoped that the mothers will learn a series of life skills which they can use to reduce stress, improve their mood and build closeness to their baby. Participants will be given a £5 Amazon voucher as a thank you for their time. The set of questionnaires that mothers are asked to complete before and after the study ask about symptoms of low mood, anxiety and depression. Most people do not mind answering these questions, but some people may feel upset. It is important that these questions are asked to find out if the online package is effective. Sometimes when people find out more about low mood and stress they can feel worse to start with. However, this is usually just for a short time and most people feel better again quite quickly as they work through online courses like this one.

Where is the study run from?

The study will take place online and mothers can complete this wherever and whenever is most convenient for them.

When is the study starting and how long is it expected to run for?

July 2015 to July 2016

Who is funding the study?

University of Glasgow (UK)

Who is the main contact?

Miss Claire Adey

Trial website

<http://www.lifeskills4mums.com/>

Contact information

Type

Public

Primary contact

Miss Claire Adey

ORCID ID

Contact details

University of Glasgow

Institute of Mental Health and Wellbeing

Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

G12 0XH

United Kingdom

Type

Scientific

Additional contact

Miss Claire Adey

ORCID ID

Contact details

University of Glasgow

Institute of Mental Health and Wellbeing

Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

G12 0XH

United Kingdom

Additional identifiers

EudraCT number

ClinicalTrials.gov number

Protocol/serial number

N/A

Study information

Scientific title

Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial

Acronym

Study hypothesis

1. It is possible to recruit up to 60 participants into the study and gather baseline and follow up data.
2. More than 50% of participants will complete the four core course modules with at least 65% data available at follow-up.
3. A reduction in the scores on the depression and anxiety measures of participants in the immediate access group will be seen when compared with the delayed access group at eight week follow-up.
4. There will be minimal or no change to participants' scores on the depression and

anxiety measures between baseline and gaining access at week eight, in the delayed access group.

5. Higher scores of satisfaction will be observed in the immediate access versus the delayed access arm.

6. There will be a higher reduction in scores on depression, anxiety and social function in the immediate access arm than in the delayed access arm.

Ethics approval

MVLS College Ethics Committee, 27/10/2015, ref: 200150010

Study design

Waiting list randomised control design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Trial setting

Internet

Trial type

Treatment

Patient information sheet

<https://dl.dropboxusercontent.com/u/9042231/Participant%20info%20sheet%201.1%20Life%20Skills%204%20Mums.pdf>

Condition

Low mood/ postnatal depression

Intervention

CBT based life skills online intervention.

The course focuses on helping mums learn a number of practical life skills (including problem solving, tackling low confidence and boosting mood) that they can use in their daily lives. It is hoped that these skills will help to relieve mild to moderate symptoms of low mood and stress. It begins with a welcome module, the first topic looks at understanding why you might feel like you do, the next how to make positive changes, the third building closeness with your baby, and finally how to look at things differently. Extra modules include topics like irritability, how to plan for the future and poor sleep.

Intervention type

Behavioural

Phase

Drug names

Primary outcome measures

Assess the ability to recruit participants, deliver the online course and to gather evaluations

Recruitment and engagement will be monitored from the study opening and throughout. Descriptive statistics will be used to describe the sample demographic details. An intention to treat protocol will be used when analysing the data obtained on the outcome measures. Descriptive statistics will be used to show how participants evaluate the intervention. A power calculation for future studies will be conducted at the end of the study and be informed by the take-up, follow-up and retention rates in the study, coupled with estimates of treatment effect gathered during the pilot phase.

Secondary outcome measures

1. PHQ-9, a self-report measure of depressive symptoms
2. Generalized Anxiety Disorder-7 (GAD-7) a self-report measure of generalized anxiety
3. Edinburgh Postnatal Depression Scale (EPDS) a 10 question self-report measure designed for use with mothers of young babies

Timepoints as of 31/03/2016:

These will be administered at baseline and at eight week follow-up

Initial timepoints:

These will be administered at baseline, eight week follow-up and 12 week follow-up

Overall trial start date

17/07/2015

Overall trial end date

29/07/2016

Reason abandoned

Eligibility

Participant inclusion criteria

1. Women over the age of 18 with a child under 18 months (amended from: a child under one year old as of 31/03/2016)
2. Not currently accessing formal mental health services e.g. a psychologist/counselor
3. Score of 5 or more on the PHQ-9 (amended from: score of 10 or more on 31/03/2016)
4. Ability to read and understand English
5. Access to the internet and able to listen to audio recordings

Participant type

Healthy volunteer

Age group

Adult

Gender

Female

Target number of participants

60 participants in total required, 30 in both the immediate access and delayed access arms.

Participant exclusion criteria

1. Women under 18 years old without a child under the age of 18 months (amended from: child under the age of 1 on 31/03/2016)
2. Already engaged with formal mental health supports e.g. attending a CMHT
3. Cannot read or understand English
4. Does not have web access as the intervention is via the internet
5. Not presenting with symptoms of low mood- assessed by a score of less than 5 on the PHQ-9 (amended from: score of less than 10 as of 31/03/2016)
6. Women who report active suicidal ideation, identified by their response to question nine on the PHQ-9 ("Thoughts that you would be better off dead or of hurting yourself in some way" either "more than half the days" or "nearly every day") will be excluded and redirected to their GP to seek immediate access to mental health services.

Recruitment start date

09/11/2015

Recruitment end date

11/01/2016

Locations

Countries of recruitment

United Kingdom

Trial participating centre

University of Glasgow

Institute of Mental Health and Wellbeing 1st floor, Administration Building Gartnavel

Royal Hospital 1055 Great Western Road

Glasgow

G12 0XH

United Kingdom

Sponsor information

Organisation

University of Glasgow, College of Medical, Veterinary and Life Sciences

Sponsor details

Institute of Mental Health and Wellbeing

Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow

G12 0XH

United Kingdom

Sponsor type

University/education

Website

Funders

Funder type

University/education

Funder name

University of Glasgow

Alternative name(s)

Funding Body Type

private sector organisation

Funding Body Subtype

academic

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The trial report and submissions of the research will be written up but participants will not be identifiable. These will be written up in a PhD thesis and submitted to the University of Glasgow in accordance with the Doctorate in Clinical Psychology course requirements and also submitted to a scientific journal. We also hope to present these at scientific conferences.

Intention to publish date

31/12/2016

Participant level data

Not expected to be available

Results - basic reporting**Publication summary****Publication citations**

Additional files

Editorial Notes

31/03/2016: Inclusion criteria, exclusion criteria and outcome follow-up data has been changed as highlighted in the appropriate fields. Intention to publish date has been added.



University
of Glasgow

College of Medical,
Veterinary & Life Sciences

Lifeskills4mums
Research Project

**Have you recently become a mum? Do
you have a child under 18 months old?**

**Low mood? Stressed
out? Anxious?
Worried? Mind
racing? Can't be
bothered doing
things? Feeling
overwhelmed? Lost
your confidence?**

← Do you feel like this?

Would you be interested in taking part in a research project of a new online resource designed specifically to help mums who have young children, and are experiencing low mood, stress or worry?

Find out more at:

www.lifeskills4mums.com

OR email

Info@lifeskills4mums.com

Appendix 3.2.4: Screen shots from the recruitment website

Welcome to Life Skills 4 Mums Research Information Site

[Home](#)[Contact Us](#)[Additional Information and supports](#)

Welcome to the Life Skills 4 Mums Research Information Site

University of Glasgow | Institute of Health & Wellbeing

Information for Potential Participants.

Enjoy your baby, life skills for mums with new babies: a pilot randomised control trial

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information (contact details at the end).

What is the purpose of the study?

Lots of people experience low mood, stress and anxiety at times throughout their life. The first year after becoming a mum is a very common time for women to feel like this. This is a really important time for mums and their babies and we would like to help make this as enjoyable as possible. Research shows that many people like to use self-help materials online or from books to gain information and skills. Evidence is growing to show that online life skills training can help and it works best if it is relevant to the people that are using it. That's why this project has been designed specifically for mums with a baby under one year old. The project has been successfully run in Canada and Wales so far.

-What does the online course include?

The course focuses on helping mums learn a number of practical life skills (including problem solving, tackling low confidence and boosting mood) that they can use in their daily lives. It is hoped that these skills will help to relieve mild to moderate symptoms of low mood and stress. It begins with a welcome module, the first topic looks at understanding why you might feel like you do, the next how to make positive changes, the third building closeness with your baby, and finally how to look at things differently. Extra modules include topics like irritability, how to plan for the future and poor sleep.

The study will randomly select half of the participants to have immediate access to the online life skills course, and the other half will be given access at the end of the study (delayed access- eight weeks later). All participants will be asked to complete some questionnaires when they sign up and then again when they complete the course. Everyone will also be asked to complete the questionnaires again after a further 4 weeks (12 weeks after starting).

Any questions: Please contact us with any questions using the Contact Us item on the menu bar above

For further information and to [read the entire Participant Information sheet CLICK HERE](#)

[Print](#) | [Sitemap](#)

Welcome to the Life Skills 4 Mums Research Information Site

University of Glasgow | Institute of Health & Wellbeing

Contact us

Contact us today!

If you have any queries or wish to contact us, please use our contact form.

You can also contact us by using the form below:

Name: *

E-mail address: *

Message: *

Captcha (spam protection code): *



 **Note:** Fields marked with * are required

Welcome to the Life Skills 4 Mums Research Information Site

University of Glasgow | Institute of Health & Wellbeing

Contact us

today!

If you have any queries or wish to contact us, please use our contact form.

Additional Information and Resources

We have created a summary of useful contacts. [CLICK HERE to download](#)

Resources and services in addition to your GP

****If you are in need of immediate support contact NHS24 on 111 or go straight to your nearest accident and emergency department****

Mental Health Problems in Pregnancy:

•

Samaritans

- Confidential support for people experiencing feelings of distress or despair.
- Phone: 08457 90 90 90 (24-hour helpline)
- Website: www.samaritans.org.uk

Breathing Space

- A confidential phoneline for anyone in Scotland feeling low, anxious or depressed
- Phone: 0800 83 85 87 (Mon-Thurs 6pm to 2am, Weekend: Fri 6pm-Mon 6am)
- Website: <http://breathingspace.scot/>

Rethink Mental Illness

- Support and advice for people living with mental illness.
- Phone: 0300 5000 927 (Mon-Fri, 10am-2pm)

Sane

- Charity offering support and carrying out research into mental illness.
- Phone: 0845 767 8000 (daily, 6pm-11pm)
- SANE email: sanemail@org.uk
- Website: www.sane.org.uk

No Panic

- Voluntary charity offering support for sufferers of panic attacks and OCD. Offers a course to help overcome your phobia/OCD. Includes a helpline.
- Phone: 0844 967 4848 (daily, 10am-10pm)
- Website: www.nopanic.org.uk

Parenting- Family Lives

- Phone: 0808 800 2222 (daily, 7am-midnight)
- Website: www.familylives.org.uk

Anxiety UK

- Charity providing support if you've been diagnosed with an anxiety condition.
- Phone: 08444 775 774 (Mon-Fri, 9.30am-5.30pm)
- Website: www.anxietyuk.org.uk

Relationships- Relate

- Phone: 0300 100 1234 (for information on their services)
- Website: www.relate.org.uk

Action on depression:

<http://www.actionondepression.org/information/depression/symptoms-of-depression?acId=Ci0KEQiAr9vmBRDdaYrH6Mi5170BEiQAcRU8i8MKO8UtheBmF2XwwwctPRutKu>

NHS: <http://www.nhs.uk/Conditions/Depression/Pages/Introduction.aspx>

<http://www.nhs.uk/conditions/Anxiety/Pages/Introduction.aspx>

<http://www.nhs.uk/conditions/stress-anxiety-depression/pages/understanding-stress.aspx>

Websites from NHS web page-

- Depression alliance: <http://www.depressionalliance.org/>
- Depression UK: <http://www.depressionuk.org/index.shtml>
- Health talk: <http://www.healthtalk.org/peoples-experiences/mental-health/depression/topics>
- Mental Health Foundation Website: <http://www.mentalhealth.org.uk/>
- Mind depression: <http://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.VNdfcZ2sWSo>
- **Royal College of Psychiatrists:**
<http://www.rcpsych.ac.uk/mentalhealthinfo/problems/depression/depression.aspx>
- Time to change: <http://www.time-to-change.org.uk/category/blog/depression>
- Students against depression: <http://studentsagainstdepression.org/>

Self- help resources:

<http://www.moodjuice.scot.nhs.uk/>

http://www.lltff.com/free_booklets/panic_book/

Northumberland guides: <http://www.ntw.nhs.uk/pic/selfhelp/>

- Self-help booklets covering a wide range of topics including Depression, Depression and Low Mood, Postnatal depression, Stress, Anxiety, Sleeping Problems, Anger, Domestic Violence and Panic.

Any queries or concerns?

Please use our contact form.

Appendix 3.2.5: Screenshots from the Enjoy Your Baby website which were also included in those shown to mothers who participated in the discussion group.

EYB Research Courses E-books Worksheets Dashboard Sign Out

Dashboard

Check your progress, take modules and manage your preferences.

Welcome!
We hope you'll find this site helpful. There are a number of useful modules and other resources available. If you're stuck for somewhere to start, we recommend the **"Welcome Module"** module.

[Get Started](#)

Need help right now? Find contact numbers on our urgent help page. [Get Help](#)

Course Progress

Enjoy Your Baby

Key information to get you back on track and help you to really enjoy your time as a mother

✓ Welcome Module
✓ Why do I feel like I do?

My Plans & Reviews [Make a plan](#)

☐ Include Archived?

Do the shopping
10/10/2018

Print off the planner sheet
10/10/2018

Manage all Plans

Courses

We have a range of courses available, designed to help you tackle many common problems.

Enjoy Your Baby

Key information to get you back on track and help you to really enjoy your time as a mother

[View Course](#)

Enjoy your Baby - Optional Modules

How to ask for what you need, get a better night's sleep, tackle irritability and plan for the future

[View Course](#)

You Time

How to get some adult time

[View Course](#)

Enjoy Your Baby

Key information to get you back on track and help you to really enjoy your time as a mother

Modules

Welcome Module
Overview of what's available and how to get the most from the course

[Take this module](#) [Get the worksheets](#)

Why do I feel like I do?
Find out key information about what makes you tick

[Take this module](#) [Get the worksheets](#)

Making positive changes
Plan activities that make you feel happier

[Take this module](#) [Get the worksheets](#)

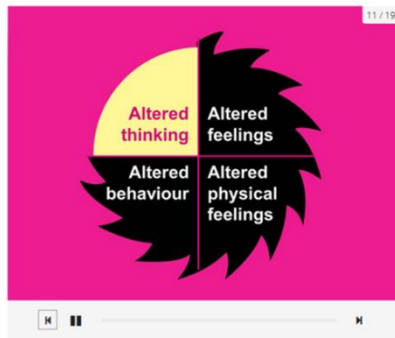
Building closeness to your baby
Some tried and trusted methods to build important bonds

[Take this module](#) [Get the worksheets](#)

Why do I feel like I do?

Part of the "Enjoy Your Baby" course.

[Return to module list](#)



[Make a plan](#) [Set a reminder](#) [E-mail support](#)

Worksheets

- Vicious circle
- The cards life deals you
- Planner Sheet
- Review Sheet

Books

Worksheets

Helping you put what you're learning into practice.

Worksheets by Course

Worksheets by E-book

All Worksheets

Enjoy Your Baby



Welcome Module

- Planner Sheet
- Review Sheet



Why do I feel like I do?

- Vicious circle
- The cards life deals you
- Planner Sheet
- Review Sheet



Making positive changes

- Happy list
- Cutting down checklist
- 10 things you can do to feel happier straight away
- Activity planner
- Planner Sheet
- Review Sheet



Building closeness to your baby

- Planner Sheet
- Review Sheet



E-books

✕ Close book

Write you're walking, really notice what's around you. The wind, the warmth, the cold, the trees, the flowers, the shops and the sky. Pretend you're seeing them for the first time, like your baby, and point them out in a loud, positive voice. He or she won't have the faintest idea what you're on about, but you'll both feel closer and happier. Your voice is the best noise on earth, remember?

People who recover from really bad times often say they appreciate things they used to take for granted. So get your coat on and go see the world for the amazing place that it is. You'll both feel better almost straight away, we promise.

27

Worksheets

- Planner Sheet
- Review Sheet
- 12 rules of assertiveness
- Easy 4-step plan
- Amazing Bad Thought Busting Programme
- 1. 2. 3. breathe
- 10 things you can do to feel happier straight away
- Mood scale - blue
- Mood scale - pink
- Bad thought spotter
- Happy list
- Activity planner

Notes

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Appendix 3.2.6: Additional analyses

Table 1: Baseline characteristics of those who completed follow-up and those who did not, and differences between these groups.

| Characteristic | Completed follow-up (n=18) (%) | Did not complete follow-up (n=23) (%) | Significance | Cramer's V |
|--|--------------------------------|---------------------------------------|--------------|------------|
| Pregnancy planned | 12 (66.7) | 19 (82.6) | $P=.289$ | .184 |
| - Not planned | 6 (33.3) | 4 (17.4) | | |
| Baby under one year old | 13 (72.2) | 19 (82.6) | $P=.471$ | .125 |
| - Not under one | 5 (27.8) | 4 (17.4) | | |
| Other children | 11 (61.1) | 12 (52.2) | $P=.752$ | .089 |
| - No other children | 7 (38.9) | 11 (47.8) | | |
| Highest education level | | | | |
| - Postgraduate degree | 4 (22.2) | 5 (21.7) | | |
| - Undergraduate degree | 9 (50) | 9 (39.1) | | |
| - HNC, HND, SVQ (level four or five) or RSA higher diploma or equivalent | 3 (16.7) | 6 (26.1) | $P=.966$ | .132 |
| - Higher grade, A levels or equivalent | 2 (11.1) | 3 (13) | | |
| Employment- Full time | 1 (5.6) | 1 (4.3) | $P=.853$ | .194 |
| - Part time | 3 (16.7) | 7 (30.4) | | |
| - Self-employed | 2 (11.1) | 1 (4.3) | | |
| - Maternity leave | 9 (50) | 11 (47.8) | | |
| - Unemployed | 3 (16.7) | 3 (13) | | |
| Medication use | 3 (16.7) | 6 (26.1) | $P=.706$ | .113 |
| - No medication | 15 (83.3) | 17 (73.9) | | |
| Previous support | 5 (27.8) | 10 (43.5) | $P=.346$ | .162 |
| - No previous support | 13 (72.2) | 13 (56.5) | | |

Table 2: Baseline differences between age and scores on measures of those who completed follow-up and those who did not.

| | Completed follow-up (n=18) Mdn (IQR) | Did not complete follow-up (n=23) Mdn (IQR) | Z statistic | Significance <i>P</i> | Pearson's <i>r</i> |
|-------|---|--|----------------|--------------------------|--------------------|
| Age | 30 (28.75, 33.25) | 31 (28, 35) | -.991 | <i>P</i> =.322 | -.154 |
| PHQ-9 | 9.5 (7, 16) | 11 (7, 13) | -0.40 | <i>P</i> =.968 | -.010 |
| GAD-7 | 8.5 (4.75, 14.75) | 10 (6, 13) | 0.90 | <i>P</i> =.354 | .141 |
| EPDS | 14.5 (7, 16.25) | 12 (11, 15) | 0.92 | <i>P</i> =.926 | .144 |

Major Research Project Proposal

Working title- “Enjoy your baby”, online CBT for mothers with new babies: a pilot
randomised control trial

2109034a

Submitted: 17th April 2015

Version 1

Word count 3553

Major Research Project- Draft Proposal

Working title: “Enjoy your baby”, online CBT for mothers with new babies: a pilot randomised control trial

Abstract

Background: With a prevalence rate of 13% postnatal depression (PND) has been described as a public global health problem which affects not only new mothers, but also their partners and their babies. CBT has been shown to be effective in the treatment of PND. It is possible that the provision of an internet course could increase access to psychologically based treatments for new mothers at a time when it might be difficult for them to attend traditional clinic based support.

Aims:

- To recruit new mothers to a pilot evaluation of a CCBT package.
- To deliver the internet course and describe take up and dropout.
- To test the ability to gather questionnaires and track participants mood over a 12 week period.
- To test the feasibility of repeating this project on a larger scale.

Methods: Mothers, who self-identify as struggling, stressed, or experiencing symptoms of low mood and anxiety will be invited to participate in an internet life skills course, modified specifically for new mothers. Mothers will be asked to complete a number of questionnaires at baseline, eight week and, for those in the immediate access arm, 12 week follow up.

Applications: To evaluate the potential usefulness of an internet life skills course that aims to improve symptoms of low mood and stress in new mothers.

Introduction

A meta-analysis reports a 13% prevalence rate of postnatal depression (PND) (O'Hara and Swain, 1996) and this has been shown to be higher (27%) in minority ethnic women (Onozawa et al. 2003). Almond (2009) stated that PND is a global public health problem, particularly as the effects of this can extend to the child and the mothers partner. SIGN Guidelines state that new mothers are at three times more risk of developing depression in the first five weeks after giving birth (SIGN 127, 2012) than at any other time in their life. However, Morrell (2006) highlights that new mothers remain at particular risk for the first year after giving birth. Untreated PND can have a negative effect on the development of the relationship and attachment between a baby and their mother (SIGN 127, 2012; Gerhardt, 2015; and Murray, 1992). Research shows that this can have long term effects for children, for example children who have anxious or depressed mothers are at risk of emotional and behavioural difficulties (Gerhardt, 2015; Murray, 1992) and children of depressed mothers are at greater risk of experiencing depression themselves before becoming adults (Gunnar and Quevedo, 2007).

A Cochrane meta-analysis showed that Cognitive Behavioural Therapy (CBT) had positive outcomes for mothers experiencing PND (Dennis and Hodnett, 2007) and this is recommended in both NICE and SIGN guidelines (NICE 192, 2014 ; SIGN 127, 2012). There is no evidence cited to date that supports the use of computerised interventions for this group specifically (SIGN 127, 2012). However, Computerised Cognitive Behavioural Therapy (CCBT) is recommended in NICE (90, 2009) and SIGN (114, 2010) Guidelines for mild to moderate depression. Delivery of these packages in a guided self-help way can increase access for individuals. It allows them to access the resources at a time and place most convenient for them rather than having to attend a clinic during standard opening hours, it is thought this would be particularly beneficial for new mothers. Computerised self-help can be worked on independently by the patient, or with minimal support from a staff member or other supporter. Self-help also allows people to remain relatively anonymous and helps them to avoid the possible stigma of attending formal mental health services (Williams, 2003). Williams (2003) adds that it allows people to take responsibility for their own self-care, to do this at their own pace and they have the flexibility to review the materials whenever they like. Kohn et al. (2004) describe a gap in the rates of depression and anxiety, and presentation at mental health services. They

describe a high prevalence of non-presentation: 53.6% of people with symptoms of depression and 57.5% of those with symptoms of generalized anxiety disorder are untreated. They estimate that less than 50% of people present to services. Community surveys have confirmed that members of the public give higher endorsements to self-help, voluntary sector and local support networks than for more formal NHS resources (Jorm and Griffiths, 2006). We hope therefore that by allowing self-referral from a wider community setting, we will reach mothers who have not presented or taken up such help via a health service setting.

To date, standardised depression packages do not take into account the specific challenges faced by new mothers and the fact that they are unable to try to improve their symptoms using the same techniques as people without new babies e.g. a new mother has little control of their sleep pattern nor can modules relating to assertiveness be implemented in the same way. This has been a significant criticism of internet packages for depression in the past, where generic packages have failed to address the needs of the individual, resulting in lower retention and completion rates than might otherwise be the case (Woodford et al. 2014).

Early intervention is a key strategy in mental health services and this is supported by government policy (The Scottish Government, 2008). The Early Years and Early Intervention framework (2008) recognised that services aimed at intervening in the earliest years has been relatively neglected and it aims to fill this gap focussing on pre-conception to age eight years.

Morrell (2006) reviewed 20 trials of treatment of PND (1989 – 2006). These included medication trials, hormone therapy trials, a variety of groups including pram-walking and social support, massage therapy, and counselling and psychological interventions (CBT, Interpersonal Therapy and Psychodynamic therapy). These interventions offered varying degrees of improvement in patients' symptoms; two showed no improvement at all, 10 were described as poor quality and methodologically flawed and 9 were noted to have small or very small samples. None of the studies reviewed used any internet interventions.

Currently SIGN guidelines (127, 2012) state that mothers mood should be checked at least once, between four and six weeks after giving birth by either their GP or health visitor (HV). If there are concerns about a mother's mood, onward referral to mental

health services can be made. HV's can offer non-directive counselling, "listening visits", to mothers and this form of non-directive counselling is recommended by NICE (192, 2014). A previous study (Morrell et al. 2009) used similar worksheets to those being used as part of the online course to be evaluated in the current study. When offered with regular support sessions delivered by a health visitor, significant improvements in mood occurred and were sustained at 6 and 12 month follow-up.

Brief overview of current Major Research Project

Mothers who self-identify as struggling, stressed, or experiencing symptoms of low mood and anxiety will be invited to participate in an online course, modified specifically for new mothers. This will be a pre-existing free access online course (Enjoy your Baby) focusing on helping mothers understand why they feel as they do, helping them to make positive changes and feel closer to their babies. It consists of four core modules, and additional optional modules covering issues such as irritability and poor sleep commonly experienced by new mothers. This will be supplemented with minimal contact support (up to one hour) from a trained support volunteer (a research assistant in the University department who has a psychology degree background). Following randomisation, half of the mothers will be given immediate access, (immediate access arm) to the course and the other half will be given access after eight weeks (delayed access arm) once the primary outcome data has been gathered. Mothers will be asked to complete a number of questionnaires at three time points to evaluate the intervention.

Aims

- To recruit new mothers using community based recruitment methods to a pilot evaluation of an online life skills course.
- To describe the sample of participants who self-identify as being in need of support.
- To deliver the online life skills course and describe take up and dropout rates in order to evaluate whether mothers complete the whole or only part of the intervention.

- To test the ability to gather questionnaires and track participants' mood (at three time points) over a 12 week period, including an eight week intervention block.
- To identify the feasibility of repeating this project on a larger scale and to contribute to power and sample size calculations for a future substantive RCT.
- To evaluate what mothers think of the intervention.

Hypotheses

1. It is possible to recruit up to 60 participants into the study and gather baseline and follow up data.
2. More than 50% of participants will complete the four core course modules with at least 65% data available at follow-up.
3. A reduction in the scores on the depression and anxiety measures of participants in the immediate access group will be seen when compared with the delayed access group. This reduction will remain at 12 week follow up.
4. There will be minimal or no change to participants' scores on the depression and anxiety measures between baseline and gaining access at week eight, in the delayed access group.
5. Higher scores of satisfaction will be observed in the immediate access versus the delayed access arm.
6. There will be a higher reduction in scores on depression, anxiety and social function in the immediate access arm than in the delayed access arm.

Plan of Investigation

Participants- Mothers with new babies in the first year of life.

Inclusion criteria/ Exclusion criteria- Mothers must have a baby under one year old and be over the age of 18 years. There are no restrictions with regards to whether the women have other children. Mothers should be able to read and understand information presented in English, have web access, broadband, and be able to listen to audio commentaries in order to be able to fully access the course content via a

computer or mobile device. Mothers participating in other current psychological therapies or counselling will be excluded. To be eligible, mothers will score more than 10 on the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer and Williams, 2001). NICE guidelines (192, 2014) recommend the use of the PHQ-9 and the Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden and Sagovsky, 1987) as screening measures. A score of more than 10 on the PHQ-9 indicates that the respondent is reporting symptoms consistent with “moderately severe” or “severe depression”. Women who report active suicidal ideation, identified by their response to question nine on the PHQ-9 (“Thoughts that you would be better off dead or of hurting yourself in some way” either “more than half the days” or “nearly every day”) will be excluded and redirected to their GP to seek immediate access to mental health services. A selection of websites and contact details for support services will be given to all participants who are excluded from recruitment.

Research Procedures

Recruitment – Mothers will be informed about the study via an advert placed in the Metro newspaper, and we will seek to place adverts on websites such as mumsnet, Action on Depression and charity sites. Posters will also be displayed in a number of community venues including libraries, swimming pools and community centres in the Ayrshire, Glasgow and Forth Valley areas. These will point to an online recruitment site providing information about the study. Participants will not be recruited via the NHS.

Consent- Informed consent will be collected online, at recruitment. This will follow good practice guidelines: British Psychological Society Good Practice Guidelines for the Conduct of Psychological Research within the NHS (Cooper et al., 2005).

Measures- The primary outcome is to assess the ability to recruit participants, deliver the online course and to gather evaluations. In the future substantive study the primary outcome will be the Edinburgh Postnatal Depression Scale (Appendix 6).

Secondary Outcome Measures: PHQ-9 (Kroenke, Spitzer and Williams, 2001) a self-report measure of depressive symptoms (Appendix 4), Generalized Anxiety Disorder-7 (GAD-7) (Spitzer, Williams and Kroenke et al. 2006) (Appendix 5), a self-report measure of generalized anxiety, and the Edinburgh Postnatal Depression Scale (EPDS)

(Cox, Holden and Sagovsky, 1987) a 10 question self-report measure designed for use with mothers of young babies. These measures have been found to be valid and reliable in a number of populations (Spitzer et al., 2000) and are widely used in clinical practice and research. The EPDS is the most widely used measure of depressive symptoms in new mothers (Dennis and Hodnett, 2007; Morrell, 2006). All measures can be used and reproduced free of charge.

As the questionnaires consist of less than 30 questions and participants are asked to give initial reactions rather than dwell on questions, it is expected that these will take between 10 and 15 minutes to complete. This will be piloted in advance of the study.

Demographic data will be obtained to allow for a description of the sample. Participants will be asked to supply details of their registered GP and give consent for the research team to contact their GP if there are concerns about risk.

Design- This project will use a waiting list randomized control design. Following recruitment to the study, participants will be randomised using the randomisation function in Microsoft Excel, to either an immediate access or a delayed access group. The delayed access group will act as the control group. The intervention consists of a CBT based life skills course including an introductory welcome session, four core modules and a maintenance phase. Optional additional modules are also available. The online course will be supplemented with up to four additional brief support contacts either by email or telephone depending on the participant's preference. These will be made by an independent research assistant based at the University of Glasgow. Measures will be administered to all participants at baseline (week 0) and eight week follow up. Measures will also be administered to the immediate access group at 12 week follow up. The same measures will be administered at each stage to allow changes to be tracked.

Data Analysis- Descriptive statistics will be used to describe the sample demographic details. An intention to treat protocol will be used when analysing the data obtained on the outcome measures. Descriptive statistics will be used to show how participants evaluate the intervention. A power calculation for future studies will be made at the end of the study and be informed by the take-up, follow-up and retention of the study, coupled with estimates of treatment effect gathered during the pilot phase.

Justification of sample size- This is a pilot project investigating the feasibility and usefulness of conducting a larger study. In line with CONSORT Guidelines (Boutron et al., 2008) we would hope to have a minimum of 27 participants in both the control and intervention groups. This would mean a minimum sample size of 54. Resources dictate that there be a maximum of 60 participants. The most up to date statistics available from the Office for National Statistics and the National Records of Scotland show there were 778,803 live births in the UK in 2013. We hope to advertise on websites accessed by mothers such as mumsnet, which reports being “the UK’s biggest network for parents, generating over 70 million page views and over 14 million visits per month”. The Metro also, reports having 3.2 million newspaper readers every day and 14.8million UK web-based users.

Health and Safety Issues

Researcher safety issues

The primary researcher will have limited direct contact with participants. It is planned that research contacts will be largely via email and these will be standardised for all participants. Questionnaires can be sent via post should participants request this. It is not expected that the primary researcher would speak to participants by telephone. Should the independent researcher who is conducting the telephone support become concerned about any participant during the telephone calls they will follow a Standardised Operating Protocol (SOP).

Participant safety issues

The “Enjoy your baby course” has been delivered in community settings both online (Wales) and in classes (Canada) without incident. The content of the course focuses on helping new mothers understand why they feel as they do, helping them to make positive changes and feel closer to their babies. As such, it is not expected that the course will cause any distress to individuals. However, should concerns be raised, or if the independent researcher who is conducting the telephone support becomes concerned, the risk management SOP will be actioned. This protocol states that CW will be informed of the risk, and the participants GP will also be contacted via telephone or fax. Participants will be advised to contact their GP or to attend Accident and Emergency

(A&E) services. They will also be given the same information as participants who were excluded from the study due to active suicidal ideation identified during screening.

Ethical Issues

This project is designed in accordance with good clinical practice guidelines (BPS) and in agreement with the Declaration of Helsinki. The project will obtain ethical approval from Glasgow University College of Medical Veterinary and Life Sciences (MVLS).

Participants will be given information about the aims and purpose of the study and asked for informed consent to participate during recruitment. They will also be given the opportunity to opt out if they prefer. Contact details for the primary researcher will be available should people wish to seek further information. Data will be collected, stored and disseminated in accordance with the Data Protection Act (1998). Personal identifiers will be separated from responses and kept in a password protected excel file. Encrypted laptops will be used to store and analyse data. Participants' will be informed they can request to have their data destroyed at any point without adverse effect to themselves.

Participants will be informed of details for individuals and services they can contact should they feel this is necessary both in the Participant Information Sheet, and also via an "urgent help" link on the course website.

The trial report and submissions will contain anonymous summaries of data. This will include a submission to the University of Glasgow in accordance with the Doctorate in Clinical Psychology course requirements and submission to a national journal.

Settings, Equipment and Financial Issues

Posters and adverts will kindly be paid for from CW's waived fee university account. Time for a research assistant to carry out follow-up telephone calls/ e-mails with participants in the immediate intervention group is already financed via an existing research project.

Incentives such as a small monetary voucher worth £5, for an online shop e.g. Amazon will be considered, as a thank you for each participant's time. Payment for this will come from CW's waived fee University account.

Paper copies of measures and information sheets will be available for the small numbers of people who may request this; however we envisage almost all data collection will be online using Survey monkey (fee already covered). The measures that have been identified for use are freely available.

Timetable

A draft MRP proposal will be submitted to the University of Glasgow in April 2015. Following necessary amendments, ethical approval will be sought from the MVLS College (summer 2015). Once obtained, recruitment and data collection will commence (expected: September 2015). Analysis of data will take place as this is obtained, however thorough analysis will begin once the immediate intervention group have completed their 12 week follow up (prior to spring 2016). As described in the "Justification of Sample Size" above we hope that there is a large enough population of new mothers who will have access to our adverts to recruit our proposed sample size of up to 60 participants. A recent study by O'Mahen et al., (2014) report recruiting 249 mothers from Netmums- 83 of whom they report met criteria for Major Depressive Disorder as defined by the DSM-IV. The Major Research Project will be submitted to the University of Glasgow along with a systematic review of literature in this area in July 2016.

Practical Applications

PND can have an effect on the development of the mother-infant bond and these early life experiences are linked to children's social and emotional development and their outcomes in adolescence and adulthood. This project aims to contribute to the evidence base for the usefulness of online computerised self-help for new mothers experiencing symptoms of low mood and anxiety.

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Appendices

Appendix 1. Plain English Summary

Title: “Enjoy your baby”, online Cognitive Behavioural Therapy (CBT) for mothers with new babies: a pilot randomised control trial

Background: Around 13% of new mothers suffer from depression soon after giving birth: Postnatal Depression (PND). PND has been described as a global public health problem not just because of the effect this has on mothers, but also on the mothers partners and their babies. Untreated PND can affect the development of the relationship between mother and baby and this can have long term outcomes for the children e.g. being at higher risk of developing depression themselves. CBT has been shown to be effective in treating PND. This study aims to pilot a new CBT based online treatment for mothers with PND. It is hoped that the online nature of the treatment will make it easier for new mothers to access than traditional, clinic based face-to-face therapy.

Aims:

- To recruit new mothers using adverts in the community, online and in a newspaper.
- To describe the participants who self-identify as being in need of support.
- To trial the delivery of an online life skills course aimed at new mothers and describe take up and dropout rates.
- To test the ability to gather questionnaires and track participants mood over a 12 week period, including an eight week intervention block.
- To identify the feasibility of repeating this project on a larger scale.
- To evaluate what mothers think of the intervention.

Method: Mothers over the age of 18 years, who have a baby less than one year old, can read and understand English, and have internet access will be invited to participate. We plan that the project will be advertised on posters in community setting such as libraries and swimming pools, online, and in a nationwide free newspaper. The adverts will invite mothers who think they are struggling, stressed, or experiencing symptoms of low mood and anxiety to participate in an online life skills intervention, called Enjoy Your Baby. This

is based on the CBT approach, with content modified specifically for new mothers. All adverts will direct mothers to a research website with further information about the study and contact details for the researchers. If mothers would like to participate, they will be asked to give informed consent and complete a series of online questionnaires. The project uses a waiting list randomized control design and participants will be randomly allocated to either an immediate access or delayed access treatment group. All participants will be asked to recomplete the standardised questionnaires at eight week follow-up and mothers in the immediate access arm will be asked to do this again at 12 week follow-up.

Ethical issues and confidentiality: This project follows good clinical practice guidelines, the Declaration of Helsinki and will obtain ethical approval. Data will be collected, stored and disseminated in accordance with the Data Protection Act (1998).

Practical applications and Dissemination: To contribute to the evidence base for the usefulness of online self-help for new mothers. The trial report and submissions will contain anonymous summaries of data, including a submission to the University of Glasgow and to a national journal.

Key reference: Almond, P., 2009. Postnatal depression: A global public health perspective, *Perspectives in Public Health*, 129, (5), pp. 221-227.

Appendix 2. Health and Safety form

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

| | |
|---|---|
| 1. Title of Project | Enjoy your baby, online CBT for mothers with new babies: a pilot randomised control trial |
| 2. Trainee | 2109034a |
| 3. University Supervisor | Professor Chris Williams |
| 4. Other Supervisor(s) | Dr Sue Turnbull |
| 5. Local Lead Clinician | Professor Chris Williams |
| 6. Participants: (age, group or sub-group, pre- or post-treatment, etc) | Between 50 and 60 mothers over 18 years old with babies in their first year of life. |
| 7. Procedures to be applied (eg, questionnaire, interview, etc) | <p>Questionnaires and online CBT based intervention course.</p> <p>Questionnaires include standardised measures: Patient Health Questionnaire-9, Generalized Anxiety Disorder-7, and the Edinburgh Postnatal Depression Scale. These will be administered at baseline, eight week follow-up, and 12 week follow-up for those in the immediate access arm.</p> <p>Demographic data will also be collected at recruitment, as will feedback evaluating the course on completion.</p> <p>The online CBT based intervention course includes four core modules to be completed</p> |

| | |
|---|---|
| | <p>over eight weeks.</p> <p>Up to four additional support contacts will take place either by telephone or email between weeks zero and six. These will follow a standardised schedule and be delivered by a worker based at UoG who has been training in providing such support.</p> |
| <p>8. Setting (where will procedures be carried out?)</p> <p>i) General</p> | <p>Procedures by the researchers will be carried out at the University of Glasgow/Gartnavel hospital sites.</p> <p>The procedures carried out by participants will take place in a location of their choosing e.g. at home.</p> |
| <p>ii) Are home visits involved</p> | <p>No</p> |
| <p>9. Potential Risk Factors Identified</p> <p>(see chart)</p> | <p>Identifying mothers with any active suicidal ideation via measures or during support telephone calls/ emails with the research assistant.</p> <p>The primary researcher will have limited direct contact with participants. It is likely that this will only be via email and these emails will be standardised for all participants. Alternative possible communications would include sending and receiving measures via post should participants request this. It is not expected that primary researcher would speak to participants by telephone.</p> |
| <p>10. Actions to minimise risk (refer to 9)</p> | <p>The “Enjoy your baby course” has been piloted in both Wales and Canada without incident. The content of the courses focuses on helping new mothers understand why they feels as they do, helping them to make positive changes and helping them to feel closer to their babies. As such, it is not expected that the course will cause any distress to individuals. However, should concerns be raised, or if the independent researcher who is conducting the telephone support/ emails becomes concerned about any participant a Standardised Operating Protocol</p> |

| | |
|--|---|
| | <p>for risk management (SOP) will be actioned. This protocol states that CW will be informed of the risk, and the participants GP will be contacted via telephone or fax (this information, along with consent to contact the GP in this circumstance will be obtained when collecting demographic data). Participants will be advised to contact their GP or to attend Accident and Emergency services. They will also be given the same information (details of supports available to contact) as participants who were excluded from the study due to active suicidal ideation being identified during screening. The online course also has an urgent help button advising people needing added help contact NHS111 or 999 , A+E and the Samaritans as well as the person's own GP.</p> |
|--|---|

Trainee signature:Date:

University supervisor signature: Date:

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

Points to consider when assessing risk. If any answer is “no” then make a case for the design being safe or reconsider the design of the study.

| Participants | |
|--|--|
| Yes✓ | No |
| This participant sample is not normally associated with dangerous or unpredictable behaviour | This participant sample is associated with impulsive, irrational or unpredictable behaviour, and/or has poor emotional control |

| Procedures | |
|---|---|
| Yes✓ | No |
| The procedures in the study are same/similar to those used by clinical psychologists with these participants and are not normally associated with production of significant distress. | These are novel procedures, are not used with this group and by their nature might produce anger, irritability or distress. |

| Settings | |
|--|--|
| Yes✓ | No |
| These are clinical or University research settings, or other institutional settings, that participants routinely attend (eg, a school). They have procedures in place to minimise risk to staff and these are thought to be adequate in the context of the proposed study. | A private or other setting where there are not health and safety procedures that are relevant to research or clinical work proceeding without risk |

Appendix 3. Research equipment form



University of Glasgow | College of Medical,
Veterinary & Life Sciences

RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES

Trainee ...2109034a.....

Year of CourseSecond Year..... **Intake Year**.....2013.....

Please refer to latest stationary costs list (available from student support team)

| Item | Details and Amount Required | Cost or Specify if to Request to Borrow from Department |
|---|---|---|
| Stationary | | Subtotal: £0.00 |
| Postage | <p>All measures, information and consent sheets to be administered, completed and returned electronically</p> <p>5 freepost letters in case printed version are requested</p> | Subtotal: £3.10 |
| Photocopying and Laser Printing (includes cost of white paper) | <p>All measures, information and consent sheets to be administered, completed and returned electronically</p> <p>Costing for 5 paper versions in case these</p> | Subtotal:£0.80 |

| | | |
|------------------------|---|--|
| | are requested | |
| Equipment and Software | Use of a university encrypted laptop to enable secure data storage and analysis Survey Monkey subscription- fee already paid by Chris Williams | Request to borrow university laptop Subtotal: £0.00 |
| Measures | Freely accessible. | Subtotal: £0.00 |
| Miscellaneous | Adverts, posters and time for research assistant to be funded from Chris William's fee waived account | Subtotal: £0.00 |
| Total | | £3.90 |

For any request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium:

Trainee Signature..... Date.....

Supervisor's Signature Date

Appendix 4. Patient Health Questionnaire- 9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "✓" to indicate your answer)

| | Not at all | Several days | More than half the days | Nearly every day |
|---|------------|--------------|-------------------------|------------------|
| 1. Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| 2. Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |
| 3. Trouble falling or staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| 4. Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| 5. Poor appetite or overeating | 0 | 1 | 2 | 3 |
| 6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| 7. Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| 8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| 9. Thoughts that you would be better off dead or of hurting yourself in some way | 0 | 1 | 2 | 3 |

FOR OFFICE CODING 0 + _____ + _____ + _____
=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

| | | | |
|--|--|--|---|
| Not difficult at all <input type="checkbox"/> | Somewhat difficult <input type="checkbox"/> | Very difficult <input type="checkbox"/> | Extremely difficult <input type="checkbox"/> |
|--|--|--|---|

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix 5. Generalized Anxiety Disorder- 7

GAD-7

| Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems? (Use "✓" to indicate your answer) | Not at all | Several days | More than half the days | Nearly every day |
|---|------------|--------------|-------------------------|------------------|
| 1. Feeling nervous, anxious or on edge | 0 | 1 | 2 | 3 |
| 2. Not being able to stop or control worrying | 0 | 1 | 2 | 3 |
| 3. Worrying too much about different things | 0 | 1 | 2 | 3 |
| 4. Trouble relaxing | 0 | 1 | 2 | 3 |
| 5. Being so restless that it is hard to sit still | 0 | 1 | 2 | 3 |
| 6. Becoming easily annoyed or irritable | 0 | 1 | 2 | 3 |
| 7. Feeling afraid as if something awful might happen | 0 | 1 | 2 | 3 |

(For office coding: Total Score T____ = ____ + ____ + ____)

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

Appendix 6. Edinburgh Postnatal Depression Scale

Edinburgh Postnatal Depression Scale¹ (EPDS)

Name: _____ Address: _____

Your Date of Birth: _____

Baby's Date of Birth: _____ Phone: _____

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

Here is an example, already completed.

I have felt happy:

- ☐ Yes, all the time
☒ Yes, most of the time This would mean: "I have felt happy most of the time" during the past week.
☐ No, not very often Please complete the other questions in the same way.
☐ No, not at all

In the past 7 days:

- | | |
|---|--|
| 1. I have been able to laugh and see the funny side of things <input type="checkbox"/> As much as I always could <input type="checkbox"/> Not quite so much now <input type="checkbox"/> Definitely not so much now <input type="checkbox"/> Not at all | *6. Things have been getting on top of me <input type="checkbox"/> Yes, most of the time I haven't been able to cope at all <input type="checkbox"/> Yes, sometimes I haven't been coping as well as usual <input type="checkbox"/> No, most of the time I have coped quite well <input type="checkbox"/> No, I have been coping as well as ever |
| 2. I have looked forward with enjoyment to things <input type="checkbox"/> As much as I ever did <input type="checkbox"/> Rather less than I used to <input type="checkbox"/> Definitely less than I used to <input type="checkbox"/> Hardly at all | *7. I have been so unhappy that I have had difficulty sleeping <input type="checkbox"/> Yes, most of the time <input type="checkbox"/> Yes, sometimes <input type="checkbox"/> Not very often <input type="checkbox"/> No, not at all |
| *3. I have blamed myself unnecessarily when things went wrong <input type="checkbox"/> Yes, most of the time <input type="checkbox"/> Yes, some of the time <input type="checkbox"/> Not very often <input type="checkbox"/> No, never | *8. I have felt sad or miserable <input type="checkbox"/> Yes, most of the time <input type="checkbox"/> Yes, quite often <input type="checkbox"/> Not very often <input type="checkbox"/> No, not at all |
| 4. I have been anxious or worried for no good reason <input type="checkbox"/> No, not at all <input type="checkbox"/> Hardly ever <input type="checkbox"/> Yes, sometimes <input type="checkbox"/> Yes, very often | *9. I have been so unhappy that I have been crying <input type="checkbox"/> Yes, most of the time <input type="checkbox"/> Yes, quite often <input type="checkbox"/> Only occasionally <input type="checkbox"/> No, never |
| *5. I have felt scared or panicky for no very good reason <input type="checkbox"/> Yes, quite a lot <input type="checkbox"/> Yes, sometimes <input type="checkbox"/> No, not much <input type="checkbox"/> No, not at all | *10. The thought of harming myself has occurred to me <input type="checkbox"/> Yes, quite often <input type="checkbox"/> Sometimes <input type="checkbox"/> Hardly ever <input type="checkbox"/> Never |

Administered/Reviewed by _____ Date _____

¹Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786 .

²Source: K. L. Wisner, B. L. Parry, C. M. Plonk, Postpartum Depression N Engl J Med vol. 347, No 3, July 18, 2002, 194-199

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